

EPA REGISTRATION NUMBER 82633-20

Material Sent for Data Extraction

Reg. # 82633-20

Description: Registration Notice

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 7/29/14

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 476717

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: D. Morgan

Phone: 305-6217 Division: BD



**U.S. ENVIRONMENTAL PROTECTION
AGENCY**

**Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460**

**EPA Registration
Number:**

82633-20

Date of Issuance:

JUL 23 2014

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:
Unconditional

Name of Pesticide Product:
Sharda Dicamba Technical

Name and Address of Registrant (include ZIP Code):

Sharda Cropchem Ltd.
c/o Wagner Regulatory Associates
P. O. Box 640
Hockessin, DE 19707

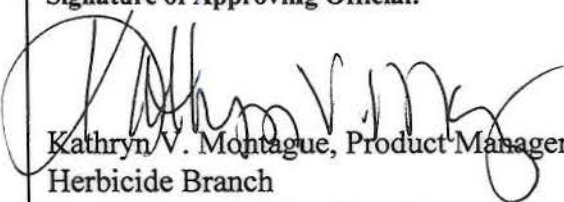
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3 (c) 5 provided that you:

1. Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Change the EPA Registration Number to: "82633-20".
3. Submit to the Agency the results of the studies for the guidelines storage stability and corrosion characteristics (830.6317 and 830.6329) within one year from the date of this Notice.
4. Submit to the Agency the results of the studies for guideline 830.6314 (oxidation/reduction) followin 830 series product properties guidelines.

Signature of Approving Official:


Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

JUL 23 2014

5. Submit one (1) copy of the revised final printed label before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Enclosure

Sharda Dicamba Technical

For Manufacturing Purposes Only

Formulators who use this product are responsible for obtaining EPA registration for their formulated end-use products.

Active Ingredient:

Dicamba (3,6-dichloro-o-anisic acid) 99.1%
 Other Ingredients: 00.9%
Total **100.0%**

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

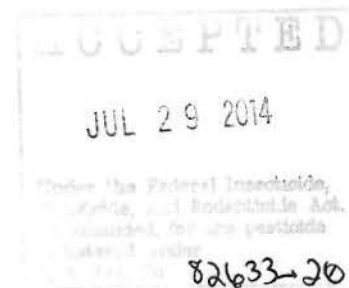
FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage. HOTLINE Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the poison control center at 1-800-222-1222 .	

See additional precautionary statements and directions for use on label.

EPA Reg. No. 82633-
Net Contents: 25, 500 kg.

EPA Est. No. _____

Manufactured for:
 SHARDA CROP-CHEM LTD.
 DOMNIC HOLM, 29TH ROAD
 BANDRA (WEST), MUMBAI - 400050

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER/PELIGRO

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be used to formulate products that are registered and/or exempt from registration by the US EPA. If the producer desires to formulate products that are not EPA approved, the producer is responsible for fulfilling all requirements for obtaining EPA registration.

Only for formulation into an herbicide for the following uses:

1. **Terrestrial Food:** Asparagus, corn, millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans and sugarcane.
2. **Terrestrial Non-food Crop:** Conservation Reserve Program Areas, Cotton, fallow systems, farmsteads, fence rows, grass forage, fodder and hay (including grasses grown for seed), golf courses, industrial areas, lawns, non-irrigation ditchbanks, pasture and rangeland, rights-of-way, roadsides, sod farms, and turf.
3. Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
4. Uses for experimental purposes that are in compliance with US EPA requirements.

The user is responsible for determining the suitability of using this product for any specific purpose, and for the manufacturing practices employed, and to ensure proper safety precautions that may be required.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original container in a well-ventilated area separately from fertilizer, feed, and foodstuffs. Avoid cross-contamination with other pesticides. For help with any spill, leak, fire or exposures involving this material call CHEMTREC 1-800-424-9300.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Sharda Cropchem Ltd. or Seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Sharda Cropchem Ltd. and Seller harmless for any claims relating to such factors.

Sharda Cropchem Ltd. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or Sharda Cropchem Ltd. and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, Sharda Cropchem Ltd., MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, neither Sharda Cropchem Ltd. or Seller shall be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SHARDA CROPCHEM LTD. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SHARDA CROPCHEM LTD. OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Sharda Cropchem Ltd. and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Sharda Cropchem Ltd.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 410792, 421143; **FILE SYMBOL No.:** 82633-EN; **PRODUCT NAME:** Sharda
Dicamba Technical; **DECISION No.:** 476717; **PC Code(s):** 029801; **ACTION CODE:** R333; **FOOD Use:**
Yes

DATE: July 7, 2014

SUBJECT: Product Chemistry Review of "Sharda Dicamba Technical"

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S. Buraker
7-7-14
JCR

TO: Dianne Morgan / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

REGISTRANT: Sharda Worldwide

USE: Herbicide

FOOD USE: Yes [X] No []

MRID Numbers: 490851-01 to 490851-12, 493933-01 & 493933-02

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Product ingredient source information may be entitled to confidential treatment

INTRODUCTION:

The registrant has submitted an application for the registration of the new technical product Sharda Dicamba technical. The registrant has submitted a CSF for basic formulation (dated March 19, 2013) and the supporting product chemistry data (group A & group B) with MRID Nos. 490851-01 to 490851-12. The Dicamba technical is produced by [REDACTED]

[REDACTED] The registrant on February 13, 2014 submitted a revised basic CSF (dated May 23, 2014) and the additional supporting data on the five batch analysis with MRID No. 493933-01 & 493933-02. The additional data is on the analysis of Polychlorinated Dioxins & Furans in the five batches of Dicamba technical. The registrant has claimed that the proposed technical is substantially similar to the registered product with Reg. No. 42750-57. TRB has been asked to evaluate and determine the acceptability of the proposed revised basic CSF (dated 05-23-2014) and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. The findings for Group A guideline data were as follows:

830.1550 (product identity & composition): The registrant has submitted a revised CSF for basic formulation (dated 05-23-2014). The product chemistry data corresponding to this guideline submitted on the CSF satisfy the data requirements of 40CFR§158.320. The nominal concentration 99.1% for AI concurs with the product label claim nominal concentration of 99.1%. The analysis for dioxins & furans shows that all dioxin congeners are below the EPA level of concern of 0.1 ppb and that average levels of all congeners for all five batches are below 0.1 ppb [MRID 490851-01 & 493933-01].

830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the dicamba technical [MRID No. 490851-02].

830.1620 (description of production process): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.330. The crude dicamba technical was produced in a [REDACTED] leading to dicamba with 99% purity. The details of the production process have been provided by the registrant [MRID No. 490851-02].

830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340. The registrant has listed [REDACTED] impurity (in the proposed revised basic CSF 05-23-2014) which was identified and detected at the concentration of >0.1% in addition to [REDACTED]. The registrant has provided the mechanisms of the formation of potential impurities in dicamba technical. The impurities of tox concern like polychlorinated dioxins & furans are present at levels of below 0.1 ppb as determined during the additional 5 batch analysis [MRID No. 490851-01 & 493933-01 & -02].

Manufacturing process information may be entitled to confidential treatment

830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline to support the claims on the CSF satisfy the data requirements of 40CFR§158.345. The five lots of the test substance were analyzed to verify the concentration of Dicamba technical. The AI content and impurities were determined by HPLC-UV method. The GC-MS in SIM mode method was used for the determination of dioxin in technical Dicamba. The analytical methods have been validated for linearity, accuracy and precision. The range of dioxin congeners were also determined by using "US EPA Method 1613 Tetra-through Octa-chlorinated Dioxins and Furans by isotope Dilution HRGC/HRMS". The results of this analysis showed that levels of 7 dioxin congeners in this batch are well below level of concern of 0.1 ppb. It was also concluded that the average Total TEQ of 5 batches is 0.02 ppb, well below 0.1 ppb [MRID No. 490851-01 & 493933-01 & -02].

830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.350. The nominal concentrations for the active ingredient and the impurities are based on the five batch analysis [MRID No. 490851-01].

830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The content of the active ingredient was determined by using Reversed phase HPLC-UV (205 nm) external standard technique. The analytical method was validated for precision, accuracy and linearity. [MRID No. 490851-03].

2. The 830 series group B guideline data (physical-chemical properties) submitted satisfy the data requirements of 40CFR§158.310(e), except for the guideline 830.6314. The registrant has requested waivers with justifications for some of the physical-chemical properties data [MRID No 490581-01].

The registrant has stated that the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) will be submitted on completion of the studies which are under progress [MRID No. 490581-01].

Product ingredient source information may be entitled to confidential treatment

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for proposed Sharda Dicamba Technical (produced by [REDACTED]) to support the proposed revised basic CSF and has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed revised CSF for basic formulation (dated 05-23-2014) is acceptable. The nominal concentration of 99.0% concurs with the product label claim nominal concentration of 99.0%. The revised basic CSF (dated 05-23-2014) will replace the previously submitted basic CSF (dated March 19, 2013).
3. The product chemistry data submitted for guideline 830 Series group B are acceptable; except for the guideline 830.6314. The registrant must submit to the Agency the results of the studies for the guidelines 830.6317 and 830.6320 on completion.
4. The registrant must conduct the studies corresponding to guideline 830.6314 (oxidation/reduction) following the 830 Series product properties guidelines. The study must be conducted to determine the compatibility and non-compatibility of the test substance towards commonly used house hold chemicals like oxidizing agents, reducing agents, kerosene, water etc.
5. The proposed product with File Symbol No. 81633-EN was determined not to be substantially similar to the cited product with Reg. No. 42750-57 from the product chemistry point of view. The impurity profile of the cited and proposed are not similar, therefore, it was concluded that two products are not substantially similar.

DP BARCODE No.: 421143, 410792; FILE SYMBOL No.: 82633-EN; PRODUCT NAME: Sharda
Dicamba Technical; DECISION No.: 476717; PC Code(s): 029801; ACTION CODE: R333; FOOD Use:
Yes

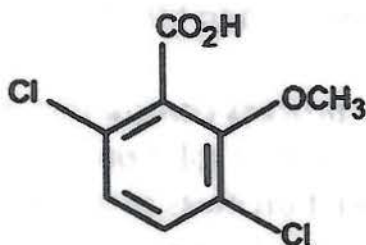
Product ingredient source information may be entitled to confidential treatment

830.1550. Product identity & composition: (MRID No. 490851-02)

PRODUCER:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Chemical Name	3,6-dichloro-2-methoxybenzoic acid
IUPAC name	3,6-dichloro-o-anisic acid
CAS Numbers:	1918-00-9



Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Group A Data

Table 1. Manufacturing and Impurity Data Sharda Dicamba Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	490851-02	A	Submitted revised basic CSF (dated 05-23-43) with NC of 99.0% for the AI.
830.1600	Description of materials used to produce the product	" "	A	Submitted the MSDS's for all the starting materials used in the synthesis of Dicamba technical at the site located at [REDACTED]
830.1620	Description of production process	" "	A	The Dicamba technical was produced in [REDACTED]. The manufacturing process has been described in detail. The quality assurance procedures adopted in each step of the process have been included.
830.1670	Discussion of formation of impurities	493933-01 490851-02	A	Impurities discussed and identified. The discussions on the mechanisms of the formation of all impurities listed on the CSF have been provided. [REDACTED] impurity has been listed in the CSF. The registrant has listed polychlorinated dioxins & furans which are present at the concentrations below the 0.1 ppb
830.1700	Preliminary analysis	490851-01 493933-02	A	The GC-MS in SIM mode method was used for the determination of dioxin in technical Dicamba. The analytical methods have been validated for linearity, accuracy and precision. The range of dioxin congeners were also determined by using "US EPA Method 1613 Tetra-through Octa-chlorinated Dioxins and Furans by isotope Dilution HRGC/HRMS". The results of this analysis showed that levels of 7 dioxin congeners in this batch are well below level of concern of 0.1 ppb. It was also concluded that the average Total TEQ of 5 batches is 0.02 ppb, well below 0.1 ppb.
830.1750	Certified limits	490851-01	A	The proposed limits for the AI and the impurities are based on five batch analysis.
830.1800	Enforcement analytical method	490851-03	A	The HPLC/UV (205 nm) method was used for the determination of the AI contents. The external standard quatification technique was used. The method was validated for precision, linearity and accuracy.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

DP BARCODE No.: 421143, 410792; FILE SYMBOL No.: 82633-EN; PRODUCT NAME: Sharda
 Dicamba Technical; DECISION No.: 476717; PC Code(s): 029801; ACTION CODE: R333; FOOD Use:
 Yes

830 Series Subgroup B (Physical-Chemical properties)

Table 2: Physical and Chemical Properties of : Sharda Dicamba TGAI/MUP				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	490851-04	A	Yellow
830.6303	Physical state	" " "	A	Solid (dry powder)
830.6304	Odor	" " "	A	Characteristic odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	490851-05 490851-06	A	Stable at room temperature and also for 2 weeks at 54°C. Stable to metals like stainless steel, Al, Cu, Fe and Brass.
830.6314	Oxidation/reduction: chemical incompatibility	490581-08	N	No study was done to show compatibility and non-compatibility to commonly used household chemicals.
830.6315	Flammability	Waiver request letter 03-19-13	W	Accepted
830.6316	Explosibility	" " "	W	Accepted
830.6317	Storage stability		G	No data submitted
830.6319	Miscibility	Waiver request letter 03-19-13	W	Accepted
830.6320	Corrosion characteristics		G	No data submitted
830.7000	pH	490851-08	A	2.11 (1% m/V) at 20.2°C
830.7050	UV/Visible absorption	475047-09 (Cited)	A	
830.7100	Viscosity	Waiver request letter 03-19-13	W	Accepted
830.7200	Melting point	letter 03-19-13 (cited)	A	115°C [CRC Handbook of Chem. & Phy. 88 th ED. 2007-2008, Boca Raton, FL, p.3-156].
830.7220	Boiling point	Waiver request letter 03-19-13	W	Accepted
830.7300	Density	490851-09	A	Tap = 0.898 g/ml at 25°C Pour = 0.728 g/cc at 25°C
830.7370	Dissociation constants in water (DC)	490851-10	A	pKa = 1.95 & K _a = 1.12 x 10 ⁻² at 25°C using 0.1 mol L ⁻¹ HCl as titrant solution
830.7550	Partition coefficient	490851-11	A	Log P _{ow} = 2.465 at 20°C; pH = 1.47
830.7840	Water solubility:	490851-12	A	Water = 5.393 g/l; acetone = 799.2639 g/l; methanol = 815.3960 g/l @ 20°C
830.7950	Vapor pressure	Letter dated 03-19-13 (cited)	A	3.38 x 10 ⁻⁵ mm Hg at 25°C Refer: SRC PhysProp Data base

DP BARCODE No.: 421143, 410792; FILE SYMBOL No.: 82633-EN; PRODUCT NAME: Sharda
 Dicamba Technical; DECISION No.: 476717; PC Code(s): 029801; ACTION CODE: R333; FOOD Use:
 Yes

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-
 grade (additional information required)

Note1. 830.7050 (UV-VIS): (MRID No. 475047-09)

A. Ultraviolet and Visible Spectrum

Instrument: Perkin-Elmer Lambda 5 UV/VIS spectrometer

Concentrations: 1.81×10^{-3} M and 3.62×10^{-3} M

Solvent: H₂O (distilled)

Scanning: 200-750 nm, 1 cm cell

Spectrum: see appendix 1

Wavelength (nm)	Molar Absorptivity (L/mol-cm)	Transition
203.1	3.42×10^4	${}^1B \leftarrow {}^1A$
230 (shoulder)	8.68×10^3 (estimate)	${}^1L_a \leftarrow {}^1A$
276.0	5.12×10^2	${}^1L_b \leftarrow {}^1A$
280 (shoulder)	5.03×10^2 (estimate)	${}^1L_b \leftarrow {}^1A$

DATA PACKAGE BEAN SHEET

Date: 08-Apr-2013

Page 1 of 2

Decision #: 476717

DP #: (410792)

PRIA 421143

Parent DP #:

Submission #: 932701

E-Sub #:

*** Registration Information ***

Registration: 82633-EN - SHARDA DICAMBA TECHNICAL

Company: 82633 - SHARDA WORLDWIDE EXPORTS PVT. LTD.

Risk Manager: RM 23 - Kathryn Montague - (703) 305-1243 Room# PY1 S-7332

Risk Manager Reviewer: Dianne Morgan DMORGAN

Sent Date:

PRIA Due Date: 11-Feb-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT; MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OI

Ingredients: 029801, Dicamba(99.1%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 08-Apr-2013

Due Back:

DP Ingredient: 029801, Dicamba

DP Title: Product Chemistry

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 11-Feb-2014

Team Name: CHEM

Science Due Date:

Reviewer Name: Syammaty

6/26/14

7/7/14

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

The registrant has submitted an application to register a new product and forwarded product chemistry data to support their registration. I am also forwarding copies of the admin materials. Please review. Thanks.

490851-01 to 490851-12

DATA PACKAGE BEAN SHEET

Date: 26-Jun-2014

Page 1 of 2

Decision #: 476717

DP #: (421143)

PRIA

Parent DP #:

Submission #: 952868

E-Sub #:

*** Registration Information ***

Registration: 82633-EN - SHARDA DICAMBA TECHNICAL

Company: 82633 - SHARDA CROPCHEM LIMITED

Risk Manager: RM 23 - Kathryn Montague - (703) 305-1243 Room# PY1 S-7332

Risk Manager Reviewer: Dianne Morgan DMORGAN

Sent Date: 29-May-2014

PRIA Due Date: 25-Apr-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF

Ingredients: 029801, Dicamba(99.1%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 26-Jun-2014

Due Back:

DP Ingredient: 029801, Dicamba

DP Title: Resubmission of New Data

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 24-Feb-2014

Team Name: Chem

Science Due Date:

Reviewer Name: Shyam Mathur

6/26/14

7/7/14

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

TO THE ATTENTION OF: Shyam Mathur

Renegotiated PRIA Due Date: July 25, 2014

The registrant has submitted new analytical data for five batches of Sharda dicamba technical. Please review for acceptability. Thanks.

MRID # 493933-01
CSF May 23, 2014

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49393302		Rodger, C. (2014) The Analysis of Polychlorinated Dioxins and Fumans in Five Batches of Dicamba. Project Number: 129. Unpublished study prepared by Scientific Analysis Laboratories Ltd. 119p.	830.1700/Preliminary analysis	Pass (04-Jun-2014)

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Sharda Cropchem Ltd. (Company No. 82633)
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Sharda Dicamba Technical, EPA Reg. No. 82633-EN, Resubmission

3. Transmittal Date

May 23, 2014

4. List of Submitted Report

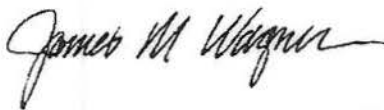
49393301

Sharda Dicamba Technical Discussion of Formation of Impurities, EPA
Guideline No. 830.1670, 6 pages.

49393302

The Analysis of Polychlorinated Dioxins and Furans in Five Batches of
Dicamba (CAS No. 1918-00-9), EPA Guideline 830.1700, Scientific
Analysis Laboratories, 119 pages.

Company Official:



Authorized Agent

James M. Wagner

Signature

Company Name: Sharda Cropchem Ltd.

Company Contact:

James M. Wagner

Authorized Agent

(302) 635-7290

Phone



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 30, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.
SHARDA CROPChem LIMITED
7217 LANCASTER PIKE, SUITE A
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 28-MAY-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 952868
Milestone Email:

Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 82633 SHARDA CROP CHEM LIMITED
Risk Manager: Registration Division, Risk Management Team 23

Resubmission: ☒ Yes ☐ No
Fee For Service: ☐ Yes ☒ No
Billable: ☐ Yes ☒ No

Print Letter
Enter More Information
Tracking

Product #: 82633-EN
Product Name: SHARDA DICAMBA TECHNICAL

Override#
Me Too Section3: 42750-57
Me Too Product Name: ALBAUGH TECHNICAL DICAMBA ACID

Application Date: 23-May-2014
Front End Date: 29-May-2014
FFS Due Date:
OPP Target Date:

OPP Rec'd Date: 28-May-2014
Risk Manager Send Date: 29-May-2014
Negotiated Due Date:

Fast Track: ☐
New Ingredient: ☐

Receipt Description:
new analytical data for five batches in response to TRB chemistry review

Form A: ☐ Signature Date:
Form B: ☐ Signature Date:

Receipt Content
Des

Study

View/Edit

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Sharda Cropchem Ltd. (Company No. 82633)
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Sharda Dicamba Technical, EPA Reg. No. 82633-EN, Resubmission

3. Transmittal Date

May 23, 2014

4. List of Submitted Report

49393301

Sharda Dicamba Technical Discussion of Formation of Impurities, EPA
Guideline No. 830.1670, 6 pages.

49393302

The Analysis of Polychlorinated Dioxins and Furans in Five Batches of
Dicamba (CAS No. 1918-00-9), EPA Guideline 830.1700, Scientific
Analysis Laboratories, 119 pages.

Company Official:



Authorized Agent

James M. Wagner

Signature

Company Name: Sharda Cropchem Ltd.

Company Contact:

James M. Wagner

Authorized Agent

(302) 635-7290

Phone

Morgan, Dianne

From: Marty Monell <Monell.Marty@epamail.epa.gov> on behalf of Workflow Messenger
<Workflow_Messenger@epamail.epa.gov>
Sent: Friday, April 25, 2014 8:27 AM
To: Monell, Marty; Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 04/22/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: 04/25/2014, , ,
Proposed New PRIA Due Date: 07/25/2014

Click on this link to access this form:

<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=6E5317F24FFF22DF85257CC2005D6255&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:

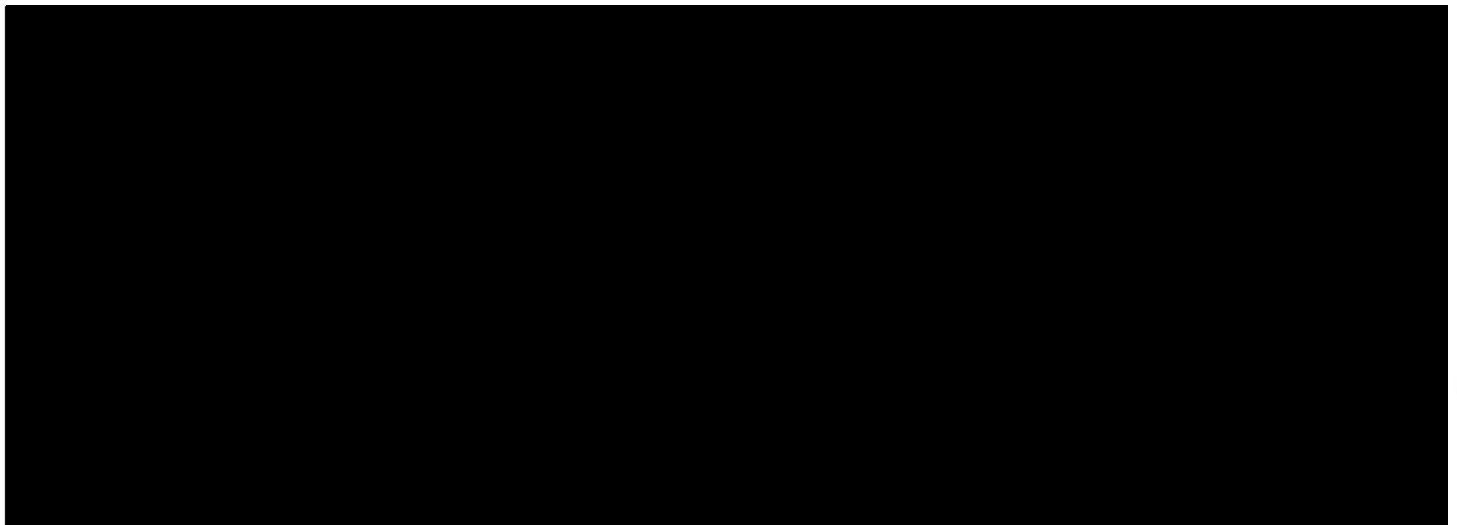
<https://webforms.epa.gov/webforms/webformsapp.nsf>

Montague, Kathryn V.

From: Montague, Kathryn V.
Sent: Tuesday, February 18, 2014 4:28 PM
To: Herndon, George
Subject: Dioxin concerns



Hi, Jeff,



Thanks,
Kay

Kathryn V. Montague
Product Manager 23
OPPTS/OPP/RD/HB
1200 Pennsylvania Ave., NW
Mailcode 7505P
Washington, DC 20460
Phone: (703)305-1243



United States
Environmental Protection Agency
 Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82633-	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sharda Dicamba Technical	PM# 23	
5. Name and Address of Applicant (Include Zip Code) Sharda Worldwide Exports Pvt. Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 42750-57 Product Name: Albaugh Technical Dicamba Acid

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
	If "Yes" No. per Unit Packaging wgt. container	If "Yes" No. per Package wgt. container		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) HDPE lined bags	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other ___ adhesive backed label _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name James M. Wagner		Title Agent for Sharda Worldwide Exports Pvt. Ltd.		Telephone No. (Include Area Code) (302) 635 7290	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 		3. Title Agent for Sharda Worldwide Exports Pvt. Ltd.			
4. Typed Name James M. Wagner		5. Date March 19, 2013			

FEDERAL EXPRESS

March 19, 2013

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



Dear Ms. Montague:

**Re: Application to register a new product containing a currently registered active ingredient -
"Sharda Dicamba Technical"**

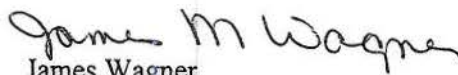
Wagner Regulatory Associates, Inc., as agent for Sharda Worldwide Exports Pvt. Ltd., is requesting registration of the above referenced product. This product is substantially similar to the dicamba product registered by Albaugh under EPA Registration Number 42750-57.

In support of this request, the following documents and studies are attached:

- Letter from Sharda Worldwide Exports Pvt. Ltd., appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- Physical and Chemical Properties data (3 copies) as outlined in the transmittal document
- Acute Toxicity data (3 copies) as outlined in the transmittal document
- Request for waiver of certain data requirements and public literature citations
- Draft labeling, 5 copies
- For "me-too" product labeling, please refer to the EPA approved label for Registration Number 42750-57, copy attached.
- A copy of the receipt confirming payment of the required registration fees.

If you have any questions about this submission please contact the undersigned.

Respectfully submitted,


James Wagner
Agent for Sharda Worldwide Exports Pvt. Ltd.

Enclosures



DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Sharda Worldwide Exports Pvt. Ltd
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Sharda Dicamba Technical

3. Transmittal Date

March 19, 2013

4. List of Submitted Studies

	OCSPP Guidelines 830.1550, 830.1670, 830.1700, 830.1800: Determination of Active Content and Impurity Profile of Dicamba
	OCSPP Guidelines 830.1600, 830.1620: Sharda Dicamba Technical: Description of Beginning Materials and Manufacturing Process
	OCSPP Guideline: 830.1800: Analytical Method Validation for the Active Ingredient Dicamba in Technical Product
	OCSPP Guideline: 830.6302, 830.6303, 830.6304: Physical State, Appearance, Color and Odor of Dicamba Technical
	OCSPP Guideline: 830.6313, 830.6317: Determination of the Thermal and Air Stability of Dicamba Technical
	OCSPP Guideline: 830.6313: Corrosiveness of Dicamba Technical
	OCSPP Guideline: 830.6315: Flammability of Dicamba Technical
	OCSPP Guideline: 830.7000: Determination of the pH value of an aqueous solution of Dicamba Technical
	OCSPP Guideline: 830.7300: Determination of the Bulk Density of Dicamba Technical
	OCSPP Guideline: 830.7370: Dissociation Constants in Water of Dicamba Technical
	OCSPP Guideline: 830.7550: Partition Coefficient (N-Octanol/Water) of Dicamba Technical

	OCSPP Guideline: 830.7840: Solubility in Water and Organic Solvents of Dicamba Technical
	OCSPP Guideline: 870.1100: Dicamba Technical: Acute Oral Toxicity Study in Rat
	OCSPP Guideline 870.1200: Dicamba Technical: Acute Dermal Toxicity Study in Rat
	OCSPP Guideline 870.1300: Dicamba Technical: Acute Inhalation Toxicity Study in Rat
	OCSPP Guideline 870.2400: Dicamba Technical: Acute Eye Irritation/Corrosion Study in Rabbits
	OCSPP Guideline 870.2500: Dicamba Technical: Acute Dermal Irritation/Corrosion Study in Rabbits
	OCSPP Guideline 870.2600: Dicamba Technical: Skin Sensitization Study (Buehler Test) in Guinea Pig

Company Official:

James M. Wagner
Authorized Agent


Signature

Company Name: Sharda Worldwide Exports Pvt. Ltd.

Company Contact:

James M. Wagner
Authorized Agent

(302) 635-7290
Phone



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sharda Worldwide Exports Pvt. Ltd., Domnic Holm, 29th Rd, Bandra (West) Mumbai, India 400050	EPA Registration Number/File Symbol 82633
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date March 19, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Use, Terrestrial Non-Food	Product Name Sharda Dicamba Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>James M. Wagner</i>	Date March 19, 2013	Typed or Printed Name and Title James M. Wagner, Agent (Tel: 302-635-7290)
-------------------------------------	------------------------	---



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 1 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1650, 830.1670,	Product identity, composition/Description of materials Used to Produce the Product/Description of Production Process/Discussion of Formation of Impurities		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.1700	Preliminary Analysis		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.1750	Certification of Limits		Sharda Worldwide Exports Pvt. Ltd.	Own	1
830.1800	Enforcement Analytical Method		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6302	Color		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6303	Odor		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6304	Physical State		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6315	Flammability		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6317	Accelerated Storage Stability		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6320	Corrosion Characteristics		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7000	pH		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7050	UV/Visible Light Absorption	47504709	Sharda Worldwide Exports Pvt. Ltd.	Old	
830.7100	Viscosity		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7200	Melting Point		Sharda Worldwide Exports Pvt. Ltd.	PL	
830.7300	Relative Density		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7370	Disseccation Constants in Water		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7550	Octanol/Water Partition Coefficient		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7840	Solubility in Organic Solvents		Sharda Worldwide Exports Pvt. Ltd.	Own	

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013 32
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 2 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7950	Vapor Pressure		Sharda Worldwide Exports Pvt. Ltd.	PL	
870.1100	Acute Oral Toxicity – rat		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.1200	Acute Dermal Toxicity – rat		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.1300	Acute Inhalation Toxicity – rat		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.2400	Eye Irritation		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.2500	Skin Irritation		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.2600	Skin Sensitization		Sharda Worldwide Exports Pvt. Ltd.	Own	
GENERIC DATA	GENERIC DATA	Cite All	Syngenta Crop Protection, Greensboro, NC	Pay	
			Agricultural Handlers Exposure Task Force, Macon, MO		
			Agricultural Reentry Task Force Washington, DC		
			Agrium Advanced Technologies, Hockessin, DE		
			Albaugh, Inc., Valdosta, GA		
			BASF Corp., RTP, NC		
			Bayer Environmental Science, RTP, NC		
			Bayer Advanced, RTP, NC		
			E.I. DuPont De Nemours and Co, Inc. Wilmington, DE		
			Chemsico, St. Louis, MO		

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013 33
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 3 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FIFRA Endangered Species Task Force, LLC, Washington, DC		
			Dow Agrosciences, Indianapolis, IN		
			Direct Ag Source, LLC, Brookfield, CT		
			Gharda Generics, Inc. Sarasota, FL		
			Gharda USA, Inc., Newtown, PA		
			Lebanon Seaboard Corp. Lebanon, PA		
			Loveland Products, Greeley, CO		
			Libertas Now, Inc., Wilmington, DE		
			Mey Corporation, Chapel Hill, NC		
			Monsanto Co., Washington, DC		
			Nufarm Americas, Inc., Morrisville, NC		
			Nufarm Inc., Morrisville, NC		
			Nufarm Limited, Morrisville, NC		
			Outdoor Residential Exposure Task Force, LLC, Washington, DC		
			PBI/Gordon Corp., Kansas City, MO		
			Petro-Canada Lubricants, Inc., Washington, DC		
			Repar Corp., Washington, DC		
			Residential Exposure Joint Venture, Washington, DC		
			Ritter Chemical, Gig Harbor, WA		

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013 34
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460


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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 4 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Spray Drift Task Force, Washington, DC		
			Scotts Company, Marysville, OH		
			Swiss Farms Products, Las Vegas, NV		
			The Andersons Lawn Fertilizer Co., Maumee, OH		
			Tacoma Ag, LLC, Brookfield, CT		
			W. Neudorff GMBH Kg, Great Falls, VA		

Footnotes: 1) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013 35
--	---	--------------------------------

FEDERAL EXPRESS

March 4, 2014

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



49332900

WRA

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Ms. Montague:

Re: Sharda Dicamba Technical, EPA Reg. No. 82633-EN, Resubmission

I am submitting new information and analytical data to address the impurity of concern identified in the recent TRB chemistry review for the pending application for registration for the referenced product. Please review the attached at your earliest convenience.

The new analytical data uses a more robust method that was developed by EPA especially for this impurity. The new data shows that the impurity level is below the Agency's level of concern. This data is for one of the original five batches submitted to the Agency with the application for registration. Sharda will now arrange to have the remaining four batches analyzed with the same EPA method. Sharda proposes to submit the report of the additional analysis to EPA as a condition of registration. Sharda will submit the report to the Agency within 60 days of the Agency's review and acceptance of this submission. A technical rationale that supports this request is included in the attached volume of data and information.

In support of this request, the following is attached:

- Letter from Sharda Cropchem Ltd., appointing Wagner Regulatory Associates, Inc. as its agent. Please note that Sharda Worldwide Exports has changed its name to Sharda Cropchem Ltd. and that the new name has already been submitted and recorded by the Agency.
- Data Transmittal Document.
- Volume: "Sharda Dicamba Technical - Discussion of Formation of Impurities" (3 copies).

If you have any questions about this resubmission please contact me.

Sincerely,

James Wagner
Agent for Sharda Cropchem Ltd.
Tel: 302-635-7290
Email: james@wagnerreg.com

Enclosures

Sharda Cropchem Limited

(Formerly known as Sharda Worldwide Exports Pvt. Ltd.)

Tel : +91 22 66782800

Fax : +91 22 66782828 / 66782808

E-mail: shardain@vsnl.com

Regd. Office : Dornic Holm, 29th Road, Bandra (W), Mumbai - 400050. India.



ISO 9001: 2008 Reg. No: 650257



February 13, 2014

To: Whom it May Concern

Re: Sharda Cropchem Ltd

This letter serves as notification that Sharda Cropchem Ltd has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding state and/or federal regulatory matters as determined by Sharda Cropchem Ltd. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

James Wagner

Email: james@wagnerreg.com

Phone: 302-635-7290

Cheryl Wagner

Email: cheryl@wagnerreg.com

Phone: 302-635-7289

Carrie Nolan

Email: carrie@wagnerreg.com

Phone: 302-635-7632

Barbarete Young-Henry

Email: barbarete@wagnerreg.com

Phone: 302-635-7279

Kt Woodall

Email: ktwoodall@wagnerreg.com

Phone: 302-635-7281

Correspondence can be addressed to any of the above employees at:

Wagner Regulatory Associates

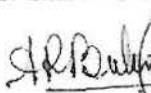
P. O. Box 640

Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates should you have any questions.

Respectfully submitted,

For Sharda Cropchem Ltd


ASHISH R. BUBNA
(DIRECTOR)

cc: WRA, Inc.

DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

Sharda Cropchem Ltd. (Company No. 82633)
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. **Regulatory Action In Support Of Which This Package Is Submitted**

Sharda Dicamba Technical, EPA Reg. No. 82633-EN, Resubmission

3. **Transmittal Date**

March 5, 2014

4. **List of Submitted Report**

49332901 Sharda Dicamba Technical, Discussion of Formation of Impurities, EPA File
No. 82633-EN, OPPTS 830.1670, Sharda Cropchem Ltd., non-confidential
portion 4 pages, confidential attachment 98 pages.

Company Official:


Authorized Agent

James M. Wagner
Signature

Company Name: Sharda Cropchem Ltd.

Company Contact:

James M. Wagner
Authorized Agent

(302) 635-7290
Phone

Sharda Cropchem Limited

(Formerly known as Sharda Worldwide Exports Pvt. Ltd.)

Tel. : +91 22 66782800

Fax : +91 22 66782828 / 66782808

E-mail: shardain@vsnl.com

Regd. Office : Dornic Holm, 29th Road, Bandra (W), Mumbai - 400050, India.



ISO 9001: 2008 Reg. No: 690257



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Phone: 302-635-7290

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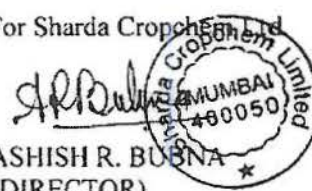
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Wagner Regulatory Associates
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Respectfully submitted,

For Sharda Cropchem Ltd


ASHISH R. BUBNA
(DIRECTOR)

cc: WRA, Inc.

Receipt for Section 3

Printer: S: 948657 Milestone Email: [Redacted]

Name: HP LaserJet 4700 Series PCL 5 Regulatory Type: Product Registration - Section 3 Status: Ready Application Type: New Registration Where: 161 80 155 247 Company: 82633 SHARDA CROP CHEM LIMITED Comment: Risk Manager: Registration Division, Risk Management Team 23 Paper: Product #: 82633-EN Product Name: SHARDA DICAMBA TECHNICAL Size: Letter Orientation: Portrait Source: Automatically Select Me Too Me Too Product Landscape Section 3: 42750-57 Name: ALBAUGH TECHNICAL DICAMBAACID

Application Date: 04-Mar-2014 OPP Rec'd Date: 06-Mar-2014 Front End Date: 06-Mar-2014 Risk Manager Send Date: 06-Mar-2014 FFS Due Date: Negotiated Due Date: OPP Target Date: Fast Track: ☐ New Ingredient: ☐ Receipt Description: new information & analytical method

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

Buttons: Print Letter, Enter More Information, Tracking, View/Edit

Receipt Content: Study

Des: [Redacted]

New Ingredient Request Date: New Ingredient Received Date: [Redacted]

Recommendation of Division Directors Negotiated Due Dates			
Decision #:476717		Registration #:82633-EN	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Dicamba			
Fee Category: R333		PRIA Decision Time Frame: 10 months	
Submitted by: Dianne Morgan		Branch: OCSPP/OPP/RD	Date: 04/22/2014
Company: Sharda Cropchem Limited			
Original PRIA Due Date: 02/11/2014		Proposed New PRIA Due Date: 07/25/2014	
Previous Negotiated Due Dates: 04/25/2014			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected:	
Negotiated Due Date Reason:			
Additional Data Required	<input checked="" type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
			<input type="checkbox"/> Environmental
			<input type="checkbox"/> Other
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
		<input type="checkbox"/> Residue	<input type="checkbox"/> Toxicology
		<input type="checkbox"/> Other	<input type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
Company was contacted April 11, 2014 to discuss the submission of the batch analyses, and the need for another negotiated due date which will allow time for the analyses and review of the additional data.			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Give us time to review the analysis that will be below our concern.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature:			Date:

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

There is an impurity of concern at detectable levels. The registrant is contending that the levels are much lower and is submitting data to support that.

Comment(s):

Morgan, Dianne

From: Montague, Kathryn V.
Sent: Tuesday, April 22, 2014 12:13 PM
To: James Wagner
Cc: Morgan, Dianne; Kenny, Daniel
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi, Jim,

July 25th will be acceptable. Dianne will draft the renegotiation paperwork today. Please let me know when you submit the new data through the front end so that we can be watching for it.

Best Regards,
Kay

From: James Wagner [mailto:jmw@wagnerreg.com]
Sent: Tuesday, April 15, 2014 10:11 AM
To: Montague, Kathryn V.
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi Kay,

Thanks for getting back to me on this. Right now the new samples are at the lab and in line for analysis with completion expected by about end of this month. So I anticipate the resubmission to be in early May. With that in mind it seems that the 60 days for TRB would end about in early July. And if we add additional time (2 weeks) for possible delays at either end, TRB should be able to finish by last week of July. So I would like to change the PRIA to July 25th. Let me know if this will be ok. Thanks.

Best regards,

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Friday, April 11, 2014 10:06 AM
To: James Wagner
Cc: Morgan, Dianne; Kenny, Daniel
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi, Jim,

I spoke with Dan about this yesterday, and he confirmed that we could not grant a conditional registration for this. So, considering that your renegotiated PRIA date is in 2 weeks (4/25/14), we need to renegotiate again to allow you time to submit the batch analyses. You indicated it would take you 60 days to develop/submit the data, and then we need time for TRB to review it. So I propose renegotiating for 120 days (4 months), making the new PRIA due date August 25, 2014. Please let me know if you agree to that new date.

Best Regards,
Kay

From: James Wagner [mailto:jmw@wagnerreg.com]
Sent: Friday, March 28, 2014 10:47 AM
To: Montague, Kathryn V.
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

OK, thanks. Have a good weekend.

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Friday, March 28, 2014 10:13 AM
To: James Wagner
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi, Jim,

I haven't been able to get even 10 minutes with Dan all week, aside from working on briefings for Jim Jones on a few major issues. It is really crazy here right now. When I mentioned your issue to him briefly late last week, he did indicate that he didn't think we would be able to do a conditional registration for this, but that we would talk about it in more detail. I hope to get some time with him early next week to discuss this, and I'll get back to you after that.

Best Regards,
Kay

From: James Wagner [mailto:jmw@wagnerreg.com]
Sent: Friday, March 28, 2014 8:50 AM
To: Montague, Kathryn V.
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Good morning Kay,

Were you ever able to catch up with Dan on this? I called him but we have not connected as yet.

Sharda has submitted samples to the testing lab and they should complete the analysis by late April.

Thanks,

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Tuesday, March 18, 2014 4:50 PM
To: James Wagner
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi, Jim,

Let me run it by Dan...we're very rarely allowing conditional registrations these days, so it may not be possible. I'll let you know what he says.

Thanks,
Kay

From: James Wagner [mailto:jmw@wagnerreg.com]
Sent: Friday, March 14, 2014 4:41 PM
To: Montague, Kathryn V.
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Thanks Kay. This is good news. What do you think of the proposal for granting a conditional registration based on the results that I submitted for the single batch? The condition being to submit the remaining analyses within 60 days. Dan Kenny and Lois Rossi approved a similar type of conditional registration for another herbicide registration that I worked on previously. I would be happy to come in and meet with you and Dan if that would be helpful.

Thanks for your consideration. Have a good weekend.

Jim Wagner
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From: Montague, Kathryn V. [mailto:Montague.Kathryn@epa.gov]
Sent: Friday, March 14, 2014 4:32 PM
To: James Wagner
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi, Jim,

Shyam said the approach seems reasonable, and he will look at the 1 batch analysis you submitted along with the remaining 4 batches when we receive them from you.

Best Regards,
Kay

From: James Wagner [mailto:jmw@wagnerreg.com]
Sent: Wednesday, March 12, 2014 6:47 PM
To: Montague, Kathryn V.
Subject: FW: Sharda Dicamba Technical - Resubmission on Impurity

Hi Kay,

I wanted to see if you had a chance to speak with Shyam and whether the approach I proposed looks like it could be acceptable for addressing the impurity issue? Sharda is arranging for the additional lab analysis and is anxious to get some feedback on this.

Thanks for your help.

Best regards,

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Mobile: 302-530-5745

From: James Wagner
Sent: Wednesday, March 05, 2014 11:29 AM
To: 'Montague, Kathryn V.'
Cc: 'Morgan, Dianne'
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity

Hi Kay,

As we discussed last week, I am submitting additional information and data for consideration by TRB, e-copy enclosed. The hard copy has been sent today by courier.

The justification for conditional registration is discussed in the attached cover letter and in the report volume. Prior to their knowing about the impurity issue Sharda had made arrangements to use the tech to formulate several million dollars of formulated product. Of course all of that is on hold pending the decision on conditional registration. After the data is reviewed Sharda will be anxious for feedback on the request for conditional registration.

Thanks for your consideration on this.

Best regards,

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Tel: 302-635-7290
Mobile: 302-530-5745

From: James Wagner
Sent: Tuesday, February 25, 2014 2:53 PM
To: 'Montague, Kathryn V.'
Cc: Morgan, Dianne
Subject: RE: Sharda Dicamba Technical

Hi Kay,

On behalf of Sharda I agree to the new date of April 25th.

Best regards,

Jim Wagner
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Tel: 302-635-7290
Mobile: 302-530-5745

From: Montague, Kathryn V. [<mailto:Montague.Kathryn@epa.gov>]
Sent: Tuesday, February 25, 2014 2:37 PM
To: James Wagner
Cc: Morgan, Dianne
Subject: RE: Sharda Dicamba Technical

Hi, Jim,

Just got back from a meeting, sorry I missed your call. I've forwarded this to Shyam to see if the study sounds like something they would consider in support of the product. I'll let you know what he says. In the meantime, we still need to renegotiate right away if we want to keep this under PRIA. Is Sharda ok with the 60-day renegotiation we proposed yesterday (new due date of April 25, 2014)?

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Hi Kay,

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First some background. In 2013 Sharda submitted to register this product in the UK with the Health & Safety Executive (HSE), Chemical Regulation Directorate. They reviewed the same 5 batch report as EPA and posed some questions to Sharda regarding the sufficiency of the dioxin analysis in the report. To resolve the issue with HSE, Sharda had one of the five batches re-analyzed by Scientific Analysis Laboratories Ltd (SAL) in Manchester, UK.

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Tel: 302-635-7290
Mobile: 302-530-5745

Morgan, Dianne

From: James Wagner [jimw@wagnerreg.com]
Sent: Wednesday, March 05, 2014 11:30 AM
To: Montague, Kathryn V.
Cc: Morgan, Dianne
Subject: RE: Sharda Dicamba Technical - Resubmission on Impurity
Attachments: Sharda Dicamba Technical 82633-EN resubmission.pdf

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Subject: RE: Sharda Dicamba Technical

Hi, Jim,

Just got back from a meeting, sorry I missed your call. I've forwarded this to Shyam to see if the study sounds like something they would consider in support of the product. I'll let you know what he says. In the meantime, we still need to renegotiate right away if we want to keep this under PRIA. Is Sharda ok with the 60-day renegotiation we proposed yesterday (new due date of April 25, 2014)?

Best Regards,
Kay

From: James Wagner [mailto:jmw@wagnerreg.com]
Sent: Tuesday, February 25, 2014 1:59 PM
To: Montague, Kathryn V.
Subject: Sharda Dicamba Technical

Hi Kay,

I will call you shortly but first wanted to put before you a proposal from Sharda.

First some background. In 2013 Sharda submitted to register this product in the UK with the Health & Safety Executive (HSE), Chemical Regulation Directorate. They reviewed the same 5 batch report as EPA and posed some questions to Sharda regarding the sufficiency of the dioxin analysis in the report. To resolve the issue with HSE, Sharda had one of the five batches re-analyzed by Scientific Analysis Laboratories Ltd (SAL) in Manchester, UK.

SAL used an EPA method 1613 (isotope dilution) which determines levels of seven 2,3,7,8 chloro dioxin congeners and ten 2,3,7,8 chloro furan congeners using high resolution GC/MS. This method is the preferred EPA method for this work and is the internationally accepted method for this type work. The AgriFor lab that conducted the 5 batch report which Shyam reviewed did not use the EPA method 1613. AgriFor actually analyzed for incorrect congeners and did not use high resolution GC/MS therefore SAL believes the AgriFor results are not robust and are not suitable an assessment of dioxins in dicamba. This is the same conclusion reached by UK HSE

The SAL analysis using EPA 1613 gave results well below the EPA level of 0.1 ppb for total dioxins. I can quickly submit the SAL analytical results with a justification that they are more technically appropriate for judging dioxin content in Sharda's Dicamba Technical than the method and results from AgriFor Lab.

I will call you shortly to discuss. Thanks for your consideration on this.

Best regards,

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

Morgan, Dianne

From: William Jordan [Jordan.William@epamail.epa.gov] on behalf of Workflow Messenger [Workflow_Messenger@epamail.epa.gov]
Sent: Tuesday, February 25, 2014 5:13 PM
To: Jordan, William; Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been completed by William Jordan.

Recommendation of Division Directors Negotiated Due Dates has been completed by William Jordan.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 02/25/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: 02/25/2014, , ,
Proposed New PRIA Due Date: 04/25/2014

Click on this link to access this form:
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Morgan, Dianne

From: Lois Rossi [Rossi.Lois@epamail.epa.gov] on behalf of Workflow Messenger
[Workflow_Messenger@epamail.epa.gov]
Sent: Tuesday, February 25, 2014 5:07 PM
To: Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been approved by Lois Rossi.

Recommendation of Division Directors Negotiated Due Dates has been approved by Lois Rossi.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 02/25/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: 02/25/2014, , ,
Proposed New PRIA Due Date: 04/25/2014

Click on this link to access this form:

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Morgan, Dianne

From: Kathryn Montague [Montague.Kathryn@epamail.epa.gov] on behalf of Workflow Messenger [Workflow_Messenger@epamail.epa.gov]
Sent: Tuesday, February 25, 2014 3:55 PM
To: Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been approved by Kathryn Montague.

Recommendation of Division Directors Negotiated Due Dates has been approved by Kathryn Montague.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 02/25/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: 02/25/2014, , ,
Proposed New PRIA Due Date: 04/25/2014

Click on this link to access this form:

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Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

Morgan, Dianne

From: Lois Rossi [Rossi.Lois@epamail.epa.gov] on behalf of Workflow Messenger
[Workflow_Messenger@epamail.epa.gov]
Sent: Tuesday, February 18, 2014 1:54 PM
To: Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been approved by Lois Rossi.

Recommendation of Division Directors Negotiated Due Dates has been approved by Lois Rossi.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 02/11/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: , , ,
Proposed New PRIA Due Date: 02/25/2014

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Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

Morgan, Dianne

From: James Wagner [jmw@wagnerreg.com]
Sent: Tuesday, February 11, 2014 3:42 PM
To: Morgan, Dianne
Cc: Cheryl Wagner
Subject: RE: Renegotiation for Extension

Dear Dianne,

As requested I agree to a 2 week extension to February 25th. I trust that if at all possible the review will be completed next week and allow you to approve the registration next week.

Best regards,

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

From: Morgan, Dianne [mailto:Morgan.Dianne@epa.gov]
Sent: Tuesday, February 11, 2014 3:30 PM
To: James Wagner
Cc: Cheryl Wagner
Subject: Renegotiation for Extension

Hello Jim,

This is a follow-up to our phone conversation in which I asked for an extension of the due date for this action which was due out today, February 11, 2014. As I explained, we have been having issues with the last possible science date and the PRIA date being the same. This is the case with this action. I spoke with the Branch Chief and Product Chemistry Manager, and was told they could get the review to me next week. I apologize for this delay, and am requesting a two week extension (2/25/14). This is the only piece that we need, all other reviews have been completed. Thanks.

Recommendation of Division Directors Negotiated Due Dates					
Decision #: 476717		Registration #: 82633-EN		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries					
Chemical Name: Dicamba					
Fee Category: R333				PRIA Decision Time Frame: 10 months	
Submitted by: Dianne				Branch: OCSPP/OPP/RD	
		Morgan		Date: 02/25/2014	
Company: Sharda Cropchem Limited					
Original PRIA Due Date: 02/11/2014			Proposed New PRIA Due Date: 04/25/2014		
Previous Negotiated Due Dates: 02/25/2014					
Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a If not, date "Fix" expected: 03/05/2014					
Negotiated Due Date Reason:					
Additional Data Required <input checked="" type="checkbox"/> Product Chemistry <input type="checkbox"/> Efficacy		<input type="checkbox"/> Toxicology <input type="checkbox"/> Ecological		<input type="checkbox"/> Acute Tox <input type="checkbox"/> Residue <input type="checkbox"/> Environmental <input type="checkbox"/> Other	
Data Deficiencies <input type="checkbox"/> Product Chemistry <input type="checkbox"/> Environmental		<input type="checkbox"/> Acute Tox <input type="checkbox"/> Ecological		<input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
Late Risk Assessment <input type="checkbox"/> Human Health		<input type="checkbox"/> Ecological			
Interim Consideration <input type="checkbox"/> CSF <input type="checkbox"/> Impurities Review		<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Label		<input type="checkbox"/> Registrant Initiated <input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health <input type="checkbox"/> Administrative-FR Notice <input type="checkbox"/> Other – Comment Field	
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)					
Product Chemistry: <input checked="" type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>					
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): Company was contacted Feb. 24, 2014, to discuss an impurity in the product chemistry review and the need for another negotiated due date to review additional data.					
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>					
Rationale for Proposed Due Date: Give us time to review a SAL analysis that will be below our concern.					
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable					
Approve: <input checked="" type="checkbox"/>			Disapprove: <input type="checkbox"/>		
If disapproved, action to be taken:					
OD or DOD Signature: CN=William Jordan/OU=DC/O=USEPA/C=US					Date: 02/25/2014

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

The issue revolves around whether there are other dicamba technical products with as high or higher levels of a specific impurity in the product. The company wants to submit an analysis conducted by Scientific Analysis laboratories LTD (SAL) that gave results well below the Agency's level of concern.

Comment(s):

Issue discovered shortly prior to PRIA due date - not a true data deficiency, although some additional information may be submitted for TRB to review.

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf

Form Number: PRIA

Document Identifier: PRIA-14056145620-DM

SUBMITTED on 02/25/2014 at 03:53:47 PM by CN=Dianne Morgan/OU=DC/O=USEPA/C=US

APPROVED on 02/25/2014 at 03:55:24 PM by CN=Kathryn Montague/OU=DC/O=USEPA/C=US

APPROVED on 02/25/2014 at 05:07:21 PM by CN=Lois Rossi/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 02/25/2014 at 05:13:02 PM by CN=William Jordan/OU=DC/O=USEPA/C=US

Morgan, Dianne

From: Marty Monell [Monell.Marty@epamail.epa.gov] on behalf of Workflow Messenger [Workflow_Messenger@epamail.epa.gov]
Sent: Wednesday, February 19, 2014 7:19 AM
To: Monell, Marty; Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 02/11/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: , , ,
Proposed New PRIA Due Date: 02/25/2014

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Morgan, Dianne

From: Kathryn Montague [Montague.Kathryn@epamail.epa.gov] on behalf of Workflow Messenger [Workflow_Messenger@epamail.epa.gov]
Sent: Tuesday, February 11, 2014 5:04 PM
To: Morgan, Dianne
Subject: Recommendation of Division Directors Negotiated Due Dates has been approved by Kathryn Montague.

Recommendation of Division Directors Negotiated Due Dates has been approved by Kathryn Montague.

Author: Dianne Morgan
Chemical: Dicamba
Form Date: 02/11/2014
Decision #: 476717

Registration #: 82633-EN

Petition #:

Original PRIA Due Date: 02/11/2014
Previous Negotiated Due Dates: , , ,
Proposed New PRIA Due Date: 02/25/2014

Click on this link to access this form:
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Click on this link to access all your forms:
<https://webforms.epa.gov/webforms/webformsapp.nsf>

Morgan, Dianne

To: jmw@wagnerreg.com
Cc: cheryl@wagnerreg.com
Subject: Renegotiation for Extension

Hello Jim,

This is a follow-up to our phone conversation in which I asked for an extension of the due date for this action which was due out today, February 11, 2014. As I explained, we have been having issues with the last possible science date and the PRIA date being the same. This is the case with this action. I spoke with the Branch Chief and Product Chemistry Manager, and was told they could get the review to me next week. A apologize for this delay, and am requesting a two week extension (2/25/14). This is the only piece that we need, all other reviews have been completed.

Morgan, Dianne

From: Morgan, Dianne
Sent: Thursday, February 06, 2014 12:39 PM
To: 'cheryl@wagnerreg.com'
Cc: 'jmw@wagnerreg.com'
Subject: Needed Revision to 82633-EN
Attachments: 82633-EN-V2-6Feb2014epacomments.pdf

Hi Cheryl,

Kay forwarded me the revised label . There is still one more revision required in the "Environmental Hazards Section" see attachment. Please revise ASAP today so I forward for signature. Thanks

Montague, Kathryn V.

From: Montague, Kathryn V.
Sent: Wednesday, February 05, 2014 4:39 PM
To: 'James Wagner'
Cc: Morgan, Dianne
Subject: RE: Sharda Dicamba Technical: 82633-EN; D-476717

Hi, Jim,

Dianne is out of the office today, so here are the label revisions we need you to make:

1. Revise the "Note to Physician" to read, "Probable mucosal damage may contraindicate the use of gastric lavage."
2. Under the oral statement in the First Aid section, replace "the poison control center..." with, "a poison control center."
3. Revise the Environmental Hazard Statement to read, "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA".
4. Revise the Hazards to Humans and Domestic Animals statement to read: "Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

Please provide the revised label to us no later than COB Friday, February 7, so that we may review and stamp it in time for the PRIA due date of Tuesday, February 11.

Best Regards,
Kay

From: James Wagner [<mailto:jmw@wagnerreg.com>]
Sent: Wednesday, February 05, 2014 11:09 AM
To: Montague, Kathryn V.
Subject: Re: Sharda Dicamba Technical: 82633-EN; D-476717

Thanks!

Jim Wagner

On Feb 5, 2014, at 11:06 AM, "Montague, Kathryn V." <Montague.Kathryn@epa.gov> wrote:

Hi, Jim,

The PRIA date is 2/11. I'll double-check with Dianne on the label; there were a few changes needed, and I provided her with additional comments. She should be contacting you about them very soon – she was out earlier this week. If she's not here today, I'll send you the label comments myself so that you have time to address them. They were some minor adjustments based on the acute tox review.

Thank you,
Kay

From: James Wagner [<mailto:jmw@wagnerreg.com>]
Sent: Wednesday, February 05, 2014 10:39 AM
To: Montague, Kathryn V.
Subject: Fwd: Sharda Dicamba Technical: 82633-EN; D-476717

Hi Kay

I hope you are doing well. I just wanted to confirm the PRIA date for the subject action. I have not heard from Dianne regarding need for any label changes.

Thanks,

Jim Wagner

Begin forwarded message:

From: James Wagner <jmw@wagnerreg.com>
Date: February 3, 2014, 12:41:17 PM EST
To: "morgan.dianne@epa.gov" <morgan.dianne@epa.gov>
Subject: FW: Sharda Dicamba Technical: 82633-EN; D-476717

Hi Dianne,

I am hoping you can provide me with some information for the referenced pending action.

I have the PRIA for this action as Feb 10th - can you confirm please. And are there any label revisions needed?

Thanks for your help.

Regards,

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

From: Rowland, Grant [<mailto:Rowland.Grant@epa.gov>]
Sent: Monday, February 03, 2014 12:18 PM
To: James Wagner
Cc: Cheryl Wagner
Subject: RE: Sharda Dicamba Technical: 82633-EN; D-476717

Hello James,

This action is actually assigned to Dianne Morgan. (morgan.dianne@epa.gov) Please contact her for answers to your question. Thank you

-Grant

*Grant Rowland
Herbicide Branch
Registration Division
Office of Pesticide Programs
703-347-0254*

From: James Wagner [<mailto:jmw@wagnerreg.com>]
Sent: Monday, February 03, 2014 11:41 AM
To: Rowland, Grant
Cc: Cheryl Wagner
Subject: Sharda Dicamba Technical: 82633-EN; D-476717

Good morning Grant,

I hope the winter storm today has not dumped very much snow in your area. We have about 2 inches here in Delaware.

Questions for this pending registration – is the PRIA Feb 10th? Are there any label revisions needed?

Thanks for your help on this.

Best regards,

Jim Wagner
Regulatory Consultant
Tel: 302-635-7290
Mobile: 302-530-5745

Sharda Dicamba Technical

For Manufacturing Purposes Only

Formulators who use this product are responsible for obtaining EPA registration for their formulated end-use products.

Active Ingredient:

Dicamba (3,6-dichloro-o-anisic acid) 99.1%
 Other Ingredients: 00.9%
Total **100.0%**

KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN Have the product or container label with you when calling a poison control center or going in for treatment. HOTLINE Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 a.m. to 4:30 p.m. Pacific Time (NPIC Web site: www.npic.orst.edu)	

See additional precautionary statements and directions for use on label.

EPA Reg. No. 82633-
Net Contents: 25, 500 kg.

EPA Est. No. _____

Manufactured for:
SHARDA WORLDWIDE EXPORTS PVT. LTD.
DOMNIC HOLM, 29TH ROAD
BANDRA (WEST), MUMBAI - 400050

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER/PELIGRO

Corrosive
 Corrosive. Causes irreversible eye damage. *May be fatal* Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. *Wear long-sleeved shirt*

dermal sens State
ENVIRONMENTAL HAZARDS

in accordance with the requirements of
 Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA. *and the permitting*

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be used to formulate products that are registered and/or exempt from registration by the US EPA. If the producer desires to formulate products that are not EPA approved, the producer is responsible for fulfilling all requirements for obtaining EPA registration.

Only for formulation into an herbicide for the following uses:

1. **Terrestrial Food:** Asparagus, corn, millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans and sugarcane.
2. **Terrestrial Non-food Crop:** Conservation Reserve Program Areas, Cotton, fallow systems, farmsteads, fence rows, grass forage, fodder and hay (including grasses grown for seed) golf courses, industrial areas, lawns, non-irrigation ditchbanks, pasture and rangeland, rights-of-way, roadsides, sod farms, and turf.
3. Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
4. Uses for experimental purposes that are in compliance with US EPA requirements.

The user is responsible for determining the suitability of using this product for any specific purpose, and for the manufacturing practices employed, and to ensure proper safety precautions that may be required.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original container in a well-ventilated area separately from fertilizer, feed, and foodstuffs. Avoid cross-contamination with other pesticides. For help with any spill, leak, fire or exposures involving this material call CHEMTREC 1-800-424-9300.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Sharda Worldwide Exports Pvt. Ltd. or Seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Sharda Worldwide Exports Pvt. Ltd. and Seller harmless for any claims relating to such factors.

Sharda Worldwide Exports Pvt. Ltd. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or Sharda Worldwide Exports Pvt. Ltd. and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, Sharda Worldwide Exports Pvt. Ltd., LLC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, neither Sharda Worldwide Exports Pvt. Ltd. or Seller shall be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SHARDA WORLDWIDE EXPORTS PVT. LTD. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SHARDA WORLDWIDE EXPORTS PVT. LTD. OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Sharda Worldwide Exports Pvt. Ltd. and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Sharda Worldwide Exports Pvt. Ltd.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

January 10, 2014

MEMORANDUM: ACUTE TOXICITY DERS FOR 82633-EN

Subject: Name of Pesticide Product: SHARDA DICAMBA TECHNICAL
EPA Reg. No. /File Symbol: 82633-EN
DP Barcode: DP 410794
Decision No.: 476717
Action Code: R333
PC Codes: 029801 (Dicamba: 99.1%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Jan - 10 - 2014
of Hazard
Team Leader TOXICOLOGIST

To: Dianne Morgan/Kathryn Montague RM 23
Herbicide Branch
Registration Division (7505P)

Registrant: SHARDA WORLDWIDE EXPORTS PVT. LTD

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
029801 Dicamba	99.1%
<u>Other Ingredients:</u>	0.9%
TOTAL	100.0%

ACTION REQUESTED: The registrant has submitted an application to register a new product and forwarded a six-pack to support their registration. I am also forwarding copies of the admin. Materials. The cited 42750-17 is substantially similar..."

BACKGROUND: There are 6 acute toxicity studies (MRIDs 49085113 through 49085118, all conducted on material identified as Dicamba Technical), a cover letter (dated March 19, 2013) from Wagner Regulatory Associates, Inc., a Certification with Respect to Citation of Data

(which states the registrant is using the selective method of support or cite-all option under the selective method), a data matrix (dated 3/19/2013) which indicates the registrant owns the acute toxicity data being used to support this registration, a proposed label (with the signal word DANGER) and a CSF dated March 19, 2013.

COMMENTS AND RECOMMENDATIONS:

1. TRB has reviewed the 6 acute toxicity studies; five of these have been classified as acceptable while the dermal sensitization study (MRID 49085118) has been classified as supplementary (but upgradeable).
2. In order to upgrade the dermal sensitization study, individual data (including scores following challenge) from the cited positive control assay (Intox Study No. 12390) have to be submitted, reviewed and determined to be acceptable. On an interim basis and/or in lieu of the positive control data, the Agency can register this product with a label indicating it is a dermal sensitizer.
3. Based on the results of the five acceptable acute toxicity studies, and classifying 82633-EN as a dermal sensitizer, the following is the acute toxicity profile of 82633-EN (SHARDA DICAMBA TECHNICAL):

Acute Oral LD ₅₀	II	Acceptable	MRID 49085113
Acute Dermal LD ₅₀	III	Acceptable	MRID 49085114
Acute Inhalation LC ₅₀	IV	Acceptable	MRID 49085115
Primary Eye Irritation	I	Acceptable	MRID 49085116
Primary Dermal Irritation	IV	Acceptable	MRID 49085117
Dermal Sensitization	Positive*		(MRID 49085118)*

*Study in MRID 49085118 currently classified as supplementary data; on an interim basis and/or in lieu of individual animal positive control data, the Agency can register this product as a positive dermal sensitizer.

4. Based on the acute toxicity profile given above, as well as information in the CSF and regarding its proposed uses, the following is the precautionary and first aid labeling for 82633-EN (SHARDA DICAMBA TECHNICAL) as obtained from the Label Review System:

PRODUCT ID #: 082633-00020

PRODUCT NAME: SHARDA DICAMBA TECHNICAL

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

Hazards to Humans and Domestic Animals:

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. ~~Avoid contact with skin.~~ *KM* Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity.

The following additional statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic CSF (dated March 19, 2013) for 82633-EN should also be reviewed and accepted by the TRB Chemistry Team.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager (EPA): 23

Date: January 10, 2014

The following is the Acute Toxicity Data Evaluation Record (DER) for the previously unreviewed acute toxicity studies (MRIDs 49085113 through 49085118) supporting the registration of EPA File Symbol 82633-EN (SHARDA DICAMBA TECHNICAL).

1. DP BARCODE: 410794				
2. PC CODE: 029801 (Dicamba)				
3. CURRENT DATE: January 10, 2014				
4. TEST MATERIAL: Dicamba Technical, CAS No. 1918-00-9, an almost white crystalline fine powder, batch no. SW-010540, with a purity of 98.04%				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat / Intox Pvt. Ltd., Maharashta, India / Study No. 12680; Report No. R/12680/AOR/12 / 12 September 2012 / OCSPP 870.1100; OECD 423	49085113	3 female Wistar rats were orally dosed at 2000 mg/kg and 6 were dosed at 300 mg/kg. The test material was suspended in 0.5% carboxy methyl cellulose, but no information is provided as to the dilution. At 2000 mg/kg all 3 rats had ataxia and convulsions, and 2 were dead at 5 hrs after dosage; the remaining rat was normal 3 days after dosage and survived to termination. 6 rats were dosed at 300 mg/kg; all had ataxia at 1 and 2 hrs after dosage, and one had ataxia at 4 hrs. All were normal 5 hrs after dosage. LD ₅₀ < 2000 mg/kg; > 300 mg/kg. All had weight losses between Days 0 and 1 but all survivors had gained weight by day 15. (18-64 g) and between Days 7 and 14 (2-18 g). There were no abnormalities at necropsy.	II	A

Acute dermal toxicity / rat / Intox Pvt. Ltd., Maharashtra, India / Study No. 12681; Report No. R/12681/ADR/12 / 12 September 2012/ OCSPP 870.1200; OECD 402	49085114	5M & 5F 13-15 week old Wistar rats were dermally exposed (24 hr) to 2000 mg test material moistened with "analytical grade water." There was no mortality and there were no signs of toxicity. LD ₅₀ > 2000 mg/kg. All rats gained weight between Days 1 (day of dosage) and 7 except for 1F that lost 1 g. All gained weight between Days 7 and 15. There were no abnormalities at necropsy.	III	A
Acute inhalation toxicity / rat / Intox Pvt. Ltd., Maharashtra, India / Study No. 12682; Report No. R/12682/AIR/12 / 12 September 2012 / OCSPP 870.1300; OECD 403	49085115	5M & 5F 8 week old Wistar rats were exposed (nose-only for 4 hours) to an atmospheric concentration of 3.37 mg Dicamba Technical/L. The MMAD was 1.43 µm with a GSD of 2.74. There was no mortality (LC ₅₀ > 3.37 mg/L). Signs following removal from restraining tubes included nasal discharge, abdominal breathing, hypoactivity & ruffled appearance. All signs were gone by day 6 (day 1=day of exposure). All gained weight day 1 to 7 and again day 7 to 15. There were no abnormalities at necropsy.	IV	A
Primary eye irritation / rabbit / Intox Pvt. Ltd., Maharashtra, India / Study No. 12684; Report No. R/12684/AEI/12 / 12 September 2012 / OCSPP 870.2400; OECD 405	49085116	100 mg Dicamba Technical was instilled in the left eye of one rabbit. The treated eye was washed at 1 hr. There was persistent grade 1 corneal opacity from 24 hours through day 21. The treated eye also scored 2 for conjunctival redness at 1 hr through day 7 and for grade 2 chemosis from 24 hr through day 7.	I	A

Primary dermal irritation / rabbit / Intox Pvt. Ltd., Maharashtra, India / Study No. 12683; Report No. R/12683/ADI/12 / 12 September 2012 / OCSPP 870.2500; OECD 404	49085117	3 rabbits received 4-hr dermal exposure to 0.5 g Dicamba Technical moistened with "analytical grade water." There was no irritation (all scores were zero). PDII = 0.00.	IV	A
Dermal sensitization / Buehler assay / Guinea Pig / Intox Pvt. Ltd., Maharashtra, India / Study No. 12685; Report No. R/12685/SS/12 / 12 September 2012 / OCSPP 870.2600; OECD 406	49085118	20 (male and female, but numbers of each sex are not reported) guinea pigs were induced (dermal exposure) on days 0, 7 & 14 to 0.5 mL of a 50% w/v solution of Dicamba Technical in 80% ethanol/water on their left flanks. They were challenged (along with 10 control guinea pigs) on day 28 with a 71% w/v solution of Dicamba Technical in acetone. There was no positive response in any of the animals. Experimental part of study was completed 16 July 2012; positive control assay (summarized p. 16) was completed 15 December 2011 with DNCB (0.3% w/v in 80% ethanol/water used for induction & 0.1% w/v in acetone for challenge) with 35% positive response. However, no individual data or scores in positive assay are reported so study is currently classified as unacceptable. Study can be upgraded with individual data and scores from the positive assay.	Not a sensitizer	S

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap

DATA PACKAGE BEAN SHEET

Date: 08-Apr-2013

Page 1 of 2

Decision #: 476717

DP #: (410794)

PRIA

Parent DP #:

Submission #: 932701

E-Sub #:

*** Registration Information ***

Registration: 82633-EN - SHARDA DICAMBA TECHNICAL

Company: 82633 - SHARDA WORLDWIDE EXPORTS PVT. LTD.

Risk Manager: RM 23 - Kathryn Montague - (703) 305-1243 Room# PY1 S-7332

Risk Manager Reviewer: Dianne Morgan DMORGAN

Sent Date:

PRIA Due Date: 11-Feb-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OI

Ingredients: 029801, Dicamba(99.1%)

R333
37009

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 08-Apr-2013

Due Back:

DP Ingredient: 029801, Dicamba

DP Title: Acute Tox Data

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 11-Feb-2014

Team Name: *Top*

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

The registrant has submitted an application to register a new product and forwarded a six-pack to support their registration. I am also forwarding copies of the admin materials. the cite 42750-17 as substantially similar. Please review. Thanks.

Screening
Documents present
✓ MRIDs
✓ Label
✓ CSF
✓ Application
80 to go!

DP#: (410794)

*** Studies Sent for Review ***

Decision#: (476717)

MRID	MRID Status	Citation Reference	Guideline	85-5 Status
49085113		Randhe, M. (2012) Dicamba Technical: Acute Oral Toxicity Study in Rat. Project Number: R/12680/AOR/12. Unpublished study prepared by Intox Pvt., Ltd. 28p.	870.1100/Acute Oral Toxicity	Pass (04-Apr-2013)
49085114		Randhe, M. (2012) Dicamba Technical: Acute Dermal Toxicity Study in Rat. Project Number: R/12681/ADR/12. Unpublished study prepared by Intox Pvt., Ltd. 27p.	870.1200/Acute dermal toxicity	Pass (04-Apr-2013)
49085115		Patil, J. (2012) Dicamba Technical: Acute Inhalation Toxicity Study in Rat. Project Number: R/12681/ADR/12. Unpublished study prepared by Intox Pvt., Ltd. 34p.	870.1300/Acute inhalation toxicity	Pass (04-Apr-2013)
49085116		Randhe, M. (2012) Dicamba Technical: Acute Eye Irritation / Corrosion Study in Rabbits. Project Number: R/12684/AEI/12. Unpublished study prepared by Intox Pvt., Ltd. 30p.	870.2400/Acute eye irritation	Pass (04-Apr-2013)
49085117		Randhe, M. (2012) Dicamba Technical: Acute Dermal Irritation / Corrosion Study in Rabbits. Project Number: R/12683/ADI/12. Unpublished study prepared by Intox Pvt., Ltd. 30p.	870.2500/Acute dermal irritation	Pass (04-Apr-2013)
49085118		Randhe, M. (2012) Dicamba Technical: Skin Sensitisation Study (Buehler Test) in Guinea Pig. Project Number: R/12685/SS/12. Unpublished study prepared by Intox Pvt., Ltd. 37p.	870.2600/Skin sensitization	Pass (04-Apr-2013)

Decision Information for 82633-EN

Decision Seq: 476717 Action Code: R333, NEW PRODUCT; MUP OR EID USE PRODUCT WITH UNRE

FFS Start Date: 11-Apr-2013 Tentative Ind: No Start/Stop Clock: FQPA Clock:

Due Date: 11-Feb-2014 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 11-Apr-2013 FFS Original Decision:

Negotiated Due Date: 90-Day Due Date: 10-Jul-2013

Registrant: Predecisional Due Date: 28-Jan-2014

Current Status: PENDING (22-Mar-2013)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates 12 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 932701	Morgan, Dianne	82633-EN	11-Feb-2014	PENDING
NA				

Viewing Record 1 of 1

Good info to John 1/7/14

(R333)

Routed

4/14/13

Tech screen due 7/10/13

Final PRTA due 2/11/14 (clean label)

Pre-decisional due 1/28/14

Hi, Dianne,

New product - tox + chem data for TRB.
We need their screen done by 7/5 to meet the
90-d tech screen date - mention on beans

Thanks,
Kay

Jacket being transferred to you



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

FEDERAL EXPRESS

March 19, 2013

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Dear Ms. Montague:

**Re: Application to register a new product containing a currently registered active ingredient -
"Sharda Dicamba Technical"**

Wagner Regulatory Associates, Inc., as agent for Sharda Worldwide Exports Pvt. Ltd., is requesting registration of the above referenced product. This product is substantially similar to the dicamba product registered by Albaugh under EPA Registration Number 42750-57.

In support of this request, the following documents and studies are attached:

- Letter from Sharda Worldwide Exports Pvt. Ltd., appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- Physical and Chemical Properties data (3 copies) as outlined in the transmittal document
- Acute Toxicity data (3 copies) as outlined in the transmittal document
- Request for waiver of certain data requirements and public literature citations
- Draft labeling, 5 copies
- For "me-too" product labeling, please refer to the EPA approved label for Registration Number 42750-57, copy attached.
- A copy of the receipt confirming payment of the required registration fees.

If you have any questions about this submission please contact the undersigned.

Respectfully submitted,

James Wagner
Agent for Sharda Worldwide Exports Pvt. Ltd.

Enclosures

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Sharda Worldwide Exports Pvt. Ltd
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Sharda Dicamba Technical

3. Transmittal Date

March 19, 2013

4. List of Submitted Studies

49085101	OCSPP Guidelines 830.1550, 830.1670, 830.1700, 830.1800: Determination of Active Content and Impurity Profile of Dicamba
49085102	OCSPP Guidelines 830.1600, 830.1620: Sharda Dicamba Technical: Description of Beginning Materials and Manufacturing Process
49085103	OCSPP Guideline: 830.1800: Analytical Method Validation for the Active Ingredient Dicamba in Technical Product
49085104	OCSPP Guideline: 830.6302, 830.6303, 830.6304: Physical State, Appearance, Color and Odor of Dicamba Technical
49085105	OCSPP Guideline: 830.6313, 830.6317: Determination of the Thermal and Air Stability of Dicamba Technical
49085106	OCSPP Guideline: 830.6313: Corrosiveness of Dicamba Technical
49085107	OCSPP Guideline: 830.6315: Flammability of Dicamba Technical
49085108	OCSPP Guideline: 830.7000: Determination of the pH value of an aqueous solution of Dicamba Technical
49085109	OCSPP Guideline: 830.7300: Determination of the Bulk Density of Dicamba Technical
49085110	OCSPP Guideline: 830.7370: Dissociation Constants in Water of Dicamba Technical
49085111	OCSPP Guideline: 830.7550: Partition Coefficient (N-Octanol/Water) of Dicamba Technical

49085112	OCSP Guideline: 830.7840: Solubility in Water and Organic Solvents of Dicamba Technical
49085113	OCSP Guideline: 870.1100: Dicamba Technical: Acute Oral Toxicity Study in Rat
49085114	OCSP Guideline 870.1200: Dicamba Technical: Acute Dermal Toxicity Study in Rat
49085115	OCSP Guideline 870.1300: Dicamba Technical: Acute Inhalation Toxicity Study in Rat
49085116	OCSP Guideline 870.2400: Dicamba Technical: Acute Eye Irritation/Corrosion Study in Rabbits
49085117	OCSP Guideline 870.2500: Dicamba Technical: Acute Dermal Irritation/Corrosion Study in Rabbits
49085118	OCSP Guideline 870.2600: Dicamba Technical: Skin Sensitization Study (Buehler Test) in Guinea Pig

Company Official:

James M. Wagner
Authorized Agent


Signature

Company Name: Sharda Worldwide Exports Pvt. Ltd.

Company Contact:

James M. Wagner
Authorized Agent

(302) 635-7290
Phone

Completion of 21-Day Content Screen

PM- 23

EPA Reg. # (File Symbol) 82633-EN

Decision # D

Data package delivered to
you on 4-3-13.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

Memorandum

Date: 04 / 02 / 13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 02, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.
SHARDA WORLDWIDE EXPORTS PVT. LTD.
PO.BOX : 640
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 21-MAR-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 932701

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 82633 SHARDA WORLDWIDE EXPORTS PVT. LTD.

V

Risk Manager: Registration Division, Risk Management Team 23

Product #: 82633-EN Product Name: SHARDA DICAMBA TECHNICAL

Override#

Me Too
Section3: 42750-57

Me Too
Product Name: ALBAUGH TECHNICAL DICAMBA ACID

Application Date: 19-Mar-2013

OPP Rec'd Date: 21-Mar-2013

Front End Date: 21-Mar-2013

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

Fast Track ☐ New Ingredient ☐

Receipt Description:

Application to register a new product

New Ingredient

Request Date

New Ingredient

Received Date

Form A ☐

Signature Date:

Form B ☐

Signature Date:



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

FEDERAL EXPRESS

March 19, 2013

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Dear Ms. Montague:

**Re: Application to register a new product containing a currently registered active ingredient -
"Sharda Dicamba Technical"**

Wagner Regulatory Associates, Inc., as agent for Sharda Worldwide Exports Pvt. Ltd., is requesting registration of the above referenced product. This product is substantially similar to the dicamba product registered by Albaugh under EPA Registration Number 42750-57.

In support of this request, the following documents and studies are attached:

- Letter from Sharda Worldwide Exports Pvt. Ltd., appointing Wagner Regulatory Associates, Inc. as its agent
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- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- Physical and Chemical Properties data (3 copies) as outlined in the transmittal document
- Acute Toxicity data (3 copies) as outlined in the transmittal document
- Request for waiver of certain data requirements and public literature citations
- Draft labeling, 5 copies
- For "me-too" product labeling, please refer to the EPA approved label for Registration Number 42750-57, copy attached.
- A copy of the receipt confirming payment of the required registration fees.

If you have any questions about this submission please contact the undersigned.

Respectfully submitted,

James Wagner
Agent for Sharda Worldwide Exports Pvt. Ltd.

Enclosures

DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Sharda Worldwide Exports Pvt. Ltd
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Sharda Dicamba Technical

3. Transmittal Date

March 19, 2013

4. List of Submitted Studies

49085101	OCSPP Guidelines 830.1550, 830.1670, 830.1700, 830.1800: Determination of Active Content and Impurity Profile of Dicamba
49085102	OCSPP Guidelines 830.1600, 830.1620: Sharda Dicamba Technical: Description of Beginning Materials and Manufacturing Process
49085103	OCSPP Guideline: 830.1800: Analytical Method Validation for the Active Ingredient Dicamba in Technical Product
49085104	OCSPP Guideline: 830.6302, 830.6303, 830.6304: Physical State, Appearance, Color and Odor of Dicamba Technical
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49085113	OCSP Guideline: 870.1100: Dicamba Technical: Acute Oral Toxicity Study in Rat
49085114	OCSP Guideline 870.1200: Dicamba Technical: Acute Dermal Toxicity Study in Rat
49085115	OCSP Guideline 870.1300: Dicamba Technical: Acute Inhalation Toxicity Study in Rat
49085116	OCSP Guideline 870.2400: Dicamba Technical: Acute Eye Irritation/Corrosion Study in Rabbits
49085117	OCSP Guideline 870.2500: Dicamba Technical: Acute Dermal Irritation/Corrosion Study in Rabbits
49085118	OCSP Guideline 870.2600: Dicamba Technical: Skin Sensitization Study (Buehler Test) in Guinea Pig

Company Official:

James M. Wagner
Authorized Agent


Signature

Company Name: Sharda Worldwide Exports Pvt. Ltd.

Company Contact:

James M. Wagner
Authorized Agent

(302) 635-7290
Phone

21-Day Screen Completed by
Contractor

21-Day Expires on 4/11/13

Jacket # 82633-EN

MRID# 490851

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schaub

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 3-21-13 3/23/09

Experts In-Processing Signature: B. P. Date 3-25-13 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>82633-EN</u>		EPA Receipt Date: <u>3-21-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- Studies associated with this submission initially had some deficiencies. Study #1 had pg. 155 illegible and study #2 had pg. 4 as blank. Registrant was contacted on 03/29/13 (details in email attached). All corrections received on 04/01/13.

- Technical and impurities only, no inerts to review.

PRN 11-03 review - Passed

Ticket - Passed

J.S/04-02-13

MRID-490851

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opppdpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: James Wagner; Carrie Nolan
Phone #: 302-635-7290, 302, 635-7632
Email: james@wagnerseg.com, carrie@wagnerseg.com

First Call/Initials:

Date: 03-29-13

Time: 3:35 pm

Second Call/Initials:

Date: 04-01-13

Time: 12:25 pm

passed

This is Srijana Shrestha, EPA contractor.

I'm calling regarding your submission in support of EPA Reg # 82633-EN

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title:

Study # 1. pg 155 illegible

Volume/Study Title:

Study # 2 pg. 4 is blank.

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.

March 19, 2013
Sharda Worldwide Exports Pvt. Ltd.
EPA Company No. 82633
Application to Register "Dicamba Technical"

(1) Request for Waiver of Data Requirements: Guideline Nos. 830.6314, 6316, 6319, 6321, 7100, 7220, 7520

It is requested that the requirement for the following data be waived based on the justification provided below.

Guideline	Data Requirement	Justification for Waiver
830.6314	Oxidation/Reduction	<p>EPA Guidelines state: Required when the product contains an oxidizing or reducing agent.</p> <p>Justification: The chemical structure of Dicamba Technical indicates it is not a strong oxidizing or reducing agent.</p>
830.6316	Explosibility	<p>EPA guidelines state: Required when the product is potentially explosive.</p> <p>Justification: Sharda Dicamba Technical is not a reactive substance nor does it possess potential energy that could produce an explosion from the effect of thermal, shock or friction. Ref: http://www.fao.org</p>
830.6319	Miscibility	<p>EPA guidelines state: Required when the product is an emulsifiable liquid and is to be diluted with petroleum solvent.</p> <p>Justification: Sharda Dicamba Technical is a technical grade active ingredient and is not an emulsifiable liquid.</p>

Guideline	Data Requirement	Justification for Waiver
830.6321	Dielectric Breakdown Voltage	<p>EPA guidelines state: Required when the EP is a liquid and is to be used around electrical equipment.</p> <p>Justification: Sharda Dicamba Technical is a technical grade active ingredient, not an EP and is not intended for use around electrical equipment.</p>
830.7100	Viscosity	<p>EPA guidelines state: Required when the product is a liquid.</p> <p>Justification: Sharda Dicamba Technical is a technical grade active ingredient and its physical state is a solid at room temperature.</p>
830.7220	Boiling Point	<p>EPA guidelines state: Required when the TGAI is liquid at room temperature.</p> <p>Justification: Sharda Dicamba Technical is a technical grade active ingredient and its physical state is a solid at room temperature.</p>
830.7520	Particle Size, Fiber Length, and Diameter Distribution	<p>EPA guidelines state: Required for water insoluble test substances ($>10^{-6}$ g/l) and fibrous test substances with diameter of $\geq 0.1 \mu\text{m}$.</p> <p>Justification: Sharda Dicamba Technical is soluble in water and is not a fibrous material.</p>

(2) Public literature citations for Guideline Nos. 830.7200 and 830.7950.

The following data values were obtained from public literature references as shown below.

Guideline	Data Requirement	Value with Reference
830.7200	Melting Point	115°C Ref: Lide, D.R. CRC Handbook of Chemistry and Physics 88TH Edition 2007-2008. CRC Press, Taylor & Francis, Boca Raton, FL 2007, p. 3-156. 114-116°C Ref: Montgomery, J. H. Agrochemicals Desk Reference, 2 nd Edition 1997. Lewis Publishers, p.151.
830.7950	Vapor Pressure	3.38 x 10 ⁻⁵ mm Hg @ 25°C Ref: SRC PhysProp Database http://www.syres.com

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EPA Company No. 82633
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Guideline	Data Requirement	Justification for Waiver
830.6321	Dielectric Breakdown Voltage	<p>EPA guidelines state: Required when the EP is a liquid and is to be used around electrical equipment.</p> <p>Justification: Sharda Dicamba Technical is a technical grade active ingredient, not an EP and is not intended for use around electrical equipment.</p>
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830.7950	Vapor Pressure	3.38 x 10 ⁻⁵ mm Hg @ 25°C Ref: SRC PhysProp Database http://www.syres.com

42750-57

01-26-2012

1
4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Morris Gaskins
Registrations Manager
Albaugh, Inc.
P.O. Box 2127
Valdosta, GA 31604

JAN 26 2012

Subject: Label Amendment – Adding Use on Teff as Part of an IR-4 Action
Product Name: Albaugh Technical Dicamba Acid
EPA Registration Number: 42750-57
Submission Date: February 18, 2010
Decision Number: 440781

Dear Mr. Gaskins:

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable.

Products shipped after 18 months from the date on this notice or the next printing of the master label whichever occurs first, must bear the new label language. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA. Your release for shipment of this product constitutes acceptance of these conditions. As required, you must submit one copy of the final printed label before the product is released for shipment. If you have any questions please contact Michael Walsh by phone at (703) 308-2972 or via email at "walsh.michael@epa.gov"

Sincerely,

A handwritten signature in dark ink, appearing to read "Kathryn V. Montague".

Kathryn V. Montague
Product Manager (23)
Herbicide Branch
Registration Division (7505P)

Enclosure

ACCEPTED

JAN 26 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registration number 42750-57

ALBAUGH TECHNICAL DICAMBA ACID

FOR MANUFACTURING PURPOSES ONLY

Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

ACTIVE INGREDIENT:

Dicamba (3,6-dichloro-p-anisic acid) 98.0%

OTHER INGREDIENTS: 2.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice
IF SWALLOWED:	<ul style="list-style-type: none"> Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

See page two for additional precautionary statements.

EPA Reg. No. 42750-57

EPA Est. No. xxxxxx-xxx-xxx

NET CONTENTS: _____

MANUFACTURED FOR:

Albaugh, Inc.
Ankeny, Iowa 50021

FOR CHEMICAL SPILL, LEAK, FIRE, OR EXPOSURE CALL CHEMTREC (800) 424-9300

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your local State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For (1) The Following Use(s): Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms; (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

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PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. DO NOT reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. If not emptied in this manner, the liner may be considered an acute hazardous waste and disposed in accordance with local, state and federal regulations.

When completely empty, offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum or other outer container is contaminated and cannot be reused, dispose of in the manner required for its liner.

CONDITIONS OF SALE AND WARRANTY

The DIRECTIONS FOR USE of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of ALBAUGH, INC. or the Seller. All such risks shall be assumed by the Buyer.

ALBAUGH, INC. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALBAUGH, INC. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE OR OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY FOR ANY AND ALL CLAIMS, LOSSES, DAMAGES, OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER OR NOT BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE, SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF OR THE REPAYMENT OF THE PURCHASE PRICE FOR THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED. When Buyer suffers losses or damages resulting from the use or handling of this product (including claims based on contract, negligence, strict liability, or other legal theories), Buyer must promptly notify Seller in writing of any claims to be eligible to receive either remedy stated above. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO CASE SHALL ALBAUGH, INC. OR THE SELLER BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. ALBAUGH, INC. and the Seller offer this product, and the Buyer accepts it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of ALBAUGH, INC. No employee or agent of ALBAUGH, INC. or the Seller is authorized to vary or exceed the terms of this Warranty in any other manner.

DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

The manufacturer expressly disclaims all liability for claims and actions (whether based on contract, tort, strict liability, or breach of warranty) arising out of, resulting from or connected with a formulation containing this product when used for any purpose other than those uses set forth in the Directions for Use. The manufacturer has not developed scientific data to support, nor has it explicitly or implicitly approved, any uses other than those in the Directions for Use.

Any formulator or buyer who uses this product in formulations for any other than those stated in the Directions for Use above assumes all liability for claims and actions arising out of, connected with or resulting from such use and agrees by so using this product to indemnify and hold harmless the manufacturer from such claims and actions.

This Disclaimer and Indemnity is in addition to, not in lieu of, the above Conditions of Sale and Warranty.

Sharda Worldwide Exports Pvt.Ltd.

PHONE : OFF. : + 91 22 66782800

FAX : + 91 22 66782828 / 66782808

E-mail : shardain@vsnl.com

REGD. OFFICE : DOMNIC HOLM, 29TH ROAD, BANDRA (W), MUMBAI - 400 050. INDIA.



August 3, 2011

To: Whom it May Concern

Re: Sharda Worldwide Exports Private Limited

This letter serves as notification that Sharda Worldwide Exports Private Limited has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding state and/or federal regulatory matters as determined by Sharda Worldwide Exports Private Limited. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

James Wagner
Email: james@wagnerreg.com
Phone: 302-635-7290

Cheryl Wagner
Email: cheryl@wagnerreg.com
Phone: 302-635-7289

Catherine Byrd
Email: catherine@wagnerreg.com
Phone: 302-635-7283

Barbarette Young-Henry
Email: barbarette@wagnerreg.com
Phone: 302-635-7279

Lori Kohler
Email: lori@wagnerreg.com
Phone: 302-635-7281

Please send correspondence for Sharda Worldwide Exports Private Limited and its products to:

Wagner Regulatory Associates
P. O. Box 640
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates should you have any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ramprakash V. Bubna".

Ramprakash V. Bubna
Managing Director

cc: WRA, Inc.

Shrestha, Srijana

From: Carrie Nolan [carrie@wagnerreg.com]
Sent: Monday, April 01, 2013 12:46 PM
To: Shrestha, Srijana
Cc: Ashe, Anthony; james@wagnerreg.com
Subject: RE: Submission in Support of the Product, "Sharda Dicamba Technical" (EPA Reg# 82633-EN)
Attachments: Study #2 pg. 4.pdf

Hello –

As per your request, I've attached page 4 of Study #2.

Thank you,

Carrie Nolan

From: Carrie Nolan [mailto:carrie@wagnerreg.com]
Sent: Monday, April 01, 2013 12:13 PM
To: 'Shrestha.Srijana@epa.gov'
Cc: 'Ashe.Anthony@epa.gov'; james@wagnerreg.com
Subject: RE: Submission in Support of the Product, "Sharda Dicamba Technical" (EPA Reg# 82633-EN)

Hello –

Attached is a copy of page 155 from Study #1 that you requested.

I left a message for you in regard to page 4 from Study #2. Please call me at your earliest convenience so I may forward the required document.

Thank you,

Carrie Nolan
(302)635-7632

Determination of Active Content and Impurity Profile of Dicamba" has page 155 illegible. Please provide a revised page in which this page is legible or is marked as "BEST AVAILABLE COPY" if that is the case.

From: "Shrestha, Srijana" <Shrestha.Srijana@epa.gov>
Date: March 29, 2013 3:38:17 PM GMT-04:00
To: "james@wagnerreg.com" <james@wagnerreg.com>
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>
Subject: Submission in Support of the Product, "Sharda Dicamba Technical" (EPA Reg# 82633-EN)

Dear Mr Wagner:

This is regarding your submission in support of the product, "Sharda Dicamba Technical" (EPA Reg# 82633-EN). We have found following issues with studies associated with your submission:

- 1) Study # 1(MRID- 490851-01) titled, "Determination of Active Content and Impurity Profile of Dicamba" has page 155 illegible. Please provide a revised page in which this page is legible or is marked as "BEST AVAILABLE COPY" if that is the case.
- 2) Study #2 (MRID- 490851-02) titled, "Sharda Dicamba Technical: Description of beginning materials and Manufacturing process" has page 4 as blank. Data is missing from the following page. Please provide the revised page in which data is complete.

Please provide the revised pages to me by email. I was trying to reach you by phone but could not get hold of you. Please feel free to call me back at 703-305-6471, if you have any questions or require additional information.

Thanking you,

Srijana Shrestha
Indus Corporation, EPA Contractor
2777 S. Crystal Drive, S 4826 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 22, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-476717
EPA File Symbol or Registration Number: 82633-EN
Product Name: SHARDA DICAMBA TECHNICAL
EPA Receipt Date: 21-Mar-2013
EPA Company Number: 82633
Company Name: SHARDA WORLDWIDE EXPORTS PVT. LTD.

JAMES WAGNER
WAGNER REGULATORY ASSOCIATES, INC.
SHARDA WORLDWIDE EXPORTS PVT. LTD.
PO Box 640
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. jk", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

10
{932701r~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S- 932701

EPA File Symbol/Reg. No.

82633-EN

Pin-Punch Date:

3/21/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R333

Granted: R333

Amount Due: \$ 17,993. ¹⁹

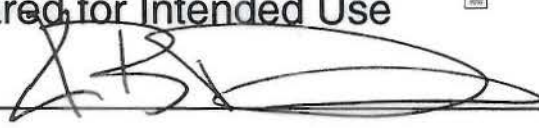
Technical & Impurities only.

NO INERTS. 3/5/04-2-13

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: 

Date: 3-22-13

Remarks:

Receipt for Section 3

S: 932701

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 82633 SHARDA WORLDWIDE EXPORTS PVT. LTD.

Risk Manager: Registration Division, Risk Management Team 23

Product #: 82633-EN

Product Name: SHARDA DICAMBA TECHNICAL

Override#:

Me Too Section3: 42750-57

Me Too Product Name: ALBAUGH TECHNICAL DICAMBA ACID

Application Date: 19-Mar-2013

Front End Date: 21-Mar-2013

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description:

Application to register a new product

Form A:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

OPP Rec'd Date: 21-Mar-2013

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

Request Date:

New Ingredient Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25A0VPB9

Agency Tracking ID: 74424771946

Transaction Date and Time: 03/19/2013 13:41 EDT

Payment Summary

Address Information

Account Holder Cheryl R.
Name: Wagner
7217 Lancaster
Billing Address: Pike
Billing Address 2: Suite A
City: Hockessin
State / Province: DE
Zip / Postal Code: 19707
Country: USA

Account Information

Card Type: American Express
Card Number: *****1000
Decision
Number:
Registration
Number:
Company Sharda Worldwide
Name: Exports
Company
Number: 82633
Action Code: R333

Payment Information

Payment Amount: \$17,993.00
Transaction Date 03/19/2013
and Time: 13:41 EDT

Cheryl Wagner

From: paygovadmin@mail.doc.twai.gov
Sent: Tuesday, March 19, 2013 1:41 PM
To: cheryl@wagnerreg.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25A0VPB9
Agency Tracking ID: 74424771946
Transaction Type: Sale
Transaction Date: Mar 19, 2013 1:41:15 PM

Account Holder Name: Cheryl R. Wagner
Transaction Amount: \$17,993.00
Billing Address: 7217 Lancaster Pike
Billing Address 2: Suite A
City: Hockessin
State/Province: DE
Zip/Postal Code: 19707
Country: USA
Card Type: AmericanExpress
Card Number: *****1000

Decision Number:
Registration Number:
Company Name: Sharda Worldwide Exports Company Number: 82633 Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



United States
Environmental Protection Agency
 Washington, DC 20460

<input checked="" type="checkbox"/> Registration	OPP Identifier Number
<input type="checkbox"/> Amendment	
<input type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 82633-	2. EPA Product Manager Kathryn Montague	3. Proposed Classification
4. Company/Product (Name) Sharda Dicamba Technical	PM# 23	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include Zip Code) Sharda Worldwide Exports Pvt. Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 42750-57 Product Name: Albaugh Technical Dicamba Acid

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other ___adhesive backed label_____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name James M. Wagner		Title Agent for Sharda Worldwide Exports Pvt. Ltd.		Telephone No. (Include Area Code) (302) 635 7290	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 		3. Title Agent for Sharda Worldwide Exports Pvt. Ltd.			
4. Typed Name James M. Wagner		5. Date March 19, 2013			

This is a reproduction of EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

FEDERAL EXPRESS

March 19, 2013

Document Processing Desk (REGFEE)
ATTN: Kathryn Montague PM 23
Registration Division (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501



Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Dear Ms. Montague:

**Re: Application to register a new product containing a currently registered active ingredient -
"Sharda Dicamba Technical"**

Wagner Regulatory Associates, Inc., as agent for Sharda Worldwide Exports Pvt. Ltd., is requesting registration of the above referenced product. This product is substantially similar to the dicamba product registered by Albaugh under EPA Registration Number 42750-57.

In support of this request, the following documents and studies are attached:

- Letter from Sharda Worldwide Exports Pvt. Ltd., appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- Physical and Chemical Properties data (3 copies) as outlined in the transmittal document
- Acute Toxicity data (3 copies) as outlined in the transmittal document
- Request for waiver of certain data requirements and public literature citations
- Draft labeling, 5 copies
- For "me-too" product labeling, please refer to the EPA approved label for Registration Number 42750-57, copy attached.
- A copy of the receipt confirming payment of the required registration fees.

If you have any questions about this submission please contact the undersigned.

Respectfully submitted,

James Wagner
Agent for Sharda Worldwide Exports Pvt. Ltd.

Enclosures



DATA TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

Sharda Worldwide Exports Pvt. Ltd
Mumbai, India
c/o Wagner Regulatory Associates
PO Box 640
Hockessin, DE 19707

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Sharda Dicamba Technical

3. Transmittal Date

March 19, 2013

4. List of Submitted Studies

OCSPP Guidelines 830.1550, 830.1670, 830.1700, 830.1800: Determination of Active Content and Impurity Profile of Dicamba

OCSPP Guidelines 830.1600, 830.1620: Sharda Dicamba Technical: Description of Beginning Materials and Manufacturing Process

OCSPP Guideline: 830.1800: Analytical Method Validation for the Active Ingredient Dicamba in Technical Product

OCSPP Guideline: 830.6302, 830.6303, 830.6304: Physical State, Appearance, Color and Odor of Dicamba Technical

OCSPP Guideline: 830.6313, 830.6317: Determination of the Thermal and Air Stability of Dicamba Technical

OCSPP Guideline: 830.6313: Corrosiveness of Dicamba Technical

OCSPP Guideline: 830.6315: Flammability of Dicamba Technical

OCSPP Guideline: 830.7000: Determination of the pH value of an aqueous solution of Dicamba Technical

OCSPP Guideline: 830.7300: Determination of the Bulk Density of Dicamba Technical

OCSPP Guideline: 830.7370: Dissociation Constants in Water of Dicamba Technical

OCSPP Guideline: 830.7550: Partition Coefficient (N-Octanol/Water) of Dicamba Technical

OCSPP Guideline: 830.7840: Solubility in Water and Organic Solvents of Dicamba
Technical

OCSPP Guideline: 870.1100: Dicamba Technical: Acute Oral Toxicity Study in Rat

OCSPP Guideline 870.1200: Dicamba Technical: Acute Dermal Toxicity Study in Rat

OCSPP Guideline 870.1300: Dicamba Technical: Acute Inhalation Toxicity Study in
Rat

OCSPP Guideline 870.2400: Dicamba Technical: Acute Eye Irritation/Corrosion Study
in Rabbits

OCSPP Guideline 870.2500: Dicamba Technical: Acute Dermal Irritation/Corrosion
Study in Rabbits

OCSPP Guideline 870.2600: Dicamba Technical: Skin Sensitization Study (Buehler
Test) in Guinea Pig

Company Official:

James M. Wagner
Authorized Agent


Signature

Company Name: Sharda Worldwide Exports Pvt. Ltd.

Company Contact:

James M. Wagner
Authorized Agent

(302) 635-7290
Phone



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sharda Worldwide Exports Pvt. Ltd., Domnic Holm, 29th Rd, Bandra (West) Mumbai, India 400050	EPA Registration Number/File Symbol 82633
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date March 19, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Use, Terrestrial Non-Food	Product Name Sharda Dicamba Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date March 19, 2013	Typed or Printed Name and Title James M. Wagner, Agent (Tel: 302-635-7290)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 1 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600, 830.1650, 830.1670,	Product identity, composition/Description of materials Used to Produce the Product/Description of Production Process/Discussion of Formation of Impurities		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.1700	Preliminary Analysis		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.1750	Certification of Limits		Sharda Worldwide Exports Pvt. Ltd.	Own	1
830.1800	Enforcement Analytical Method		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6302	Color		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6303	Odor		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6304	Physical State		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6315	Flammability		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6317	Accelerated Storage Stability		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.6320	Corrosion Characteristics		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7000	pH		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7050	UV/Visible Light Absorption	47504709	Sharda Worldwide Exports Pvt. Ltd.	Old	
830.7100	Viscosity		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7200	Melting Point		Sharda Worldwide Exports Pvt. Ltd.	PL	
830.7300	Relative Density		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7370	Dissection Constants in Water		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7550	Octanol/Water Partition Coefficient		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7840	Solubility in Organic Solvents		Sharda Worldwide Exports Pvt. Ltd.	Own	

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 2 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility		Sharda Worldwide Exports Pvt. Ltd.	Own	
830.7950	Vapor Pressure		Sharda Worldwide Exports Pvt. Ltd.	PL	
870.1100	Acute Oral Toxicity – rat		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.1200	Acute Dermal Toxicity – rat		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.1300	Acute Inhalation Toxicity – rat		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.2400	Eye Irritation		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.2500	Skin Irritation		Sharda Worldwide Exports Pvt. Ltd.	Own	
870.2600	Skin Sensitization		Sharda Worldwide Exports Pvt. Ltd.	Own	
GENERIC DATA	GENERIC DATA	Cite All	Syngenta Crop Protection, Greensboro, NC	Pay	
			Agricultural Handlers Exposure Task Force, Macon, MO		
			Agricultural Reentry Task Force Washington, DC		
			Agrium Advanced Technologies, Hockessin, DE		
			Albaugh, Inc., Valdosta, GA		
			BASF Corp., RTP, NC		
			Bayer Environmental Science, RTP, NC		
			Bayer Advanced, RTP, NC		
			E.I. DuPont De Nemours and Co, Inc. Wilmington, DE		
			Chemsico, St. Louis, MO		

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013
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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 3 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FIFRA Endangered Species Task Force, LLC, Washington, DC		
			Dow Agrosiences, Indianapolis, IN		
			Direct Ag Source, LLC, Brookfield, CT		
			Gharda Generics, Inc. Sarasota, FL		
			Gharda USA, Inc., Newtown, PA		
			Lebanon Seaboard Corp. Lebanon, PA		
			Loveland Products, Greeley, CO		
			Libertas Now, Inc., Wilmington, DE		
			Mey Corporation, Chapel Hill, NC		
			Monsanto Co., Washington, DC		
			Nufarm Americas, Inc., Morrisville, NC		
			Nufarm Inc., Morrisville, NC		
			Nufarm Limited, Morrisville, NC		
			Outdoor Residential Exposure Task Force, LLC, Washington, DC		
			PBI/Gordon Corp., Kansas City, MO		
			Petro-Canada Lubricants, Inc., Washington, DC		
			Repar Corp., Washington, DC		
			Residential Exposure Joint Venture, Washington, DC		
			Ritter Chemical, Gig Harbor, WA		

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013 129
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 3/19/2013	EPA Reg No./ File Symbol: 82633-	Page 4 of 4
Applicant's/Registrant's Name and Address: Sharda Worldwide Exports Pvt. Ltd. Domnic Holm, 29 th Road Bandra (West), Mumbai, India 400050	Product: Sharda Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Spray Drift Task Force, Washington, DC		
			Scotts Company, Marysville, OH		
			Swiss Farms Products, Las Vegas, NV		
			The Andersons Lawn Fertilizer Co., Maumee, OH		
			Tacoma Ag, LLC, Brookfield, CT		
			W. Neudorff GMBH Kg, Great Falls, VA		

Footnotes: 1) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4

Signature 	Name and Title James Wagner, Agent for Sharda Worldwide Exports Pvt. Ltd.	Date 3/19/2013 130
--	---	---------------------------------

Sharda Dicamba Technical

For Manufacturing Purposes Only

Formulators who use this product are responsible for obtaining EPA registration for their formulated end-use products.

Active Ingredient:

Dicamba (3,6-dichloro-o-anisic acid) 99.1%
 Other Ingredients: 00.9%
Total **100.0%**

KEEP OUT OF REACH OF CHILDREN
ANGER/PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

FIRST AID	
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage. HOTLINE Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 a.m. to 4:30 p.m. Pacific Time (NPIC Web site: www.npic.orst.edu)	

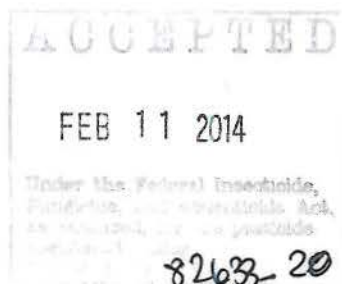
See additional precautionary statements and directions for use on label.

EPA Reg. No. 82633-
Net Contents: 25, 500 kg.

EPA Est. No. _____

Manufactured for:

SHARDA WORLDWIDE EXPORTS PVT. LTD.
 DOMNIC HOLM, 29TH ROAD
 BANDRA (WEST), MUMBAI - 400050



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER/PELIGRO**

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be used to formulate products that are registered and/or exempt from registration by the US EPA. If the producer desires to formulate products that are not EPA approved, the producer is responsible for fulfilling all requirements for obtaining EPA registration.

Only for formulation into an herbicide for the following uses:

1. **Terrestrial Food:** Asparagus, corn, millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans and sugarcane.
2. **Terrestrial Non-food Crop:** Conservation Reserve Program Areas, Cotton, fallow systems, farmsteads, fence rows, grass forage, fodder and hay (including grasses grown for seed), golf courses, industrial areas, lawns, non-irrigation ditchbanks, pasture and rangeland, rights-of-way, roadsides, sod farms, and turf.
3. Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
4. Uses for experimental purposes that are in compliance with US EPA requirements.

The user is responsible for determining the suitability of using this product for any specific purpose, and for the manufacturing practices employed, and to ensure proper safety precautions that may be required.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original container in a well-ventilated area separately from fertilizer, feed, and foodstuffs. Avoid cross-contamination with other pesticides. For help with any spill, leak, fire or exposures involving this material call CHEMTREC 1-800-424-9300.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY


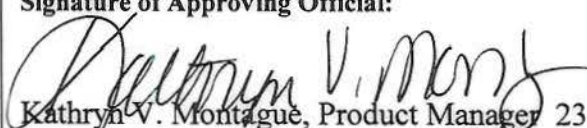
NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Sharda Worldwide Exports Pvt. Ltd. or Seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Sharda Worldwide Exports Pvt. Ltd. and Seller harmless for any claims relating to such factors.

Sharda Worldwide Exports Pvt. Ltd. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or Sharda Worldwide Exports Pvt. Ltd. and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, Sharda Worldwide Exports Pvt. Ltd., LLC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, neither Sharda Worldwide Exports Pvt. Ltd. or Seller shall be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SHARDA WORLDWIDE EXPORTS PVT. LTD. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SHARDA WORLDWIDE EXPORTS PVT. LTD. OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Sharda Worldwide Exports Pvt. Ltd. and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Sharda Worldwide Exports Pvt. Ltd.

	<p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460</p>	<p>EPA Registration Number:</p> <p>82633-20</p>	<p>Date of Issuance:</p> <p>FEB 11 2014</p>
<p align="center">NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under FIFRA, as amended)</p>		<p>Term of Issuance: Unconditional</p> <p>Name of Pesticide Product: Sharda Dicamba Technical</p>	
<p>Name and Address of Registrant (include ZIP Code): Sharda Worldwide Exports Pvt. Ltd Mumbai, India c/o Wagner Regulatory Associates P. O. Box 640 Hockessin, DE 19707</p>			
<p><small>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</small></p>			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is registered in accordance with FIFRA sec. 3 (c) (5) provided that you:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for the registration/ reregistration review of your product when the Agency requires all registrants of similar products to submit data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. 2. Change the EPA Registration Number to: 82633-20. 3. Submit one (1) copy of the revised final printed label before the product is released for shipment. <p>If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.</p> <p>A stamped copy of the label is enclosed for your records.</p> <p>Enclosure</p>			
<p>Signature of Approving Official:</p>  <p>Kathryn W. Montague, Product Manager 23 Herbicide Branch Registration Division (7505P)</p>		<p>Date:</p> <p>FEB 11 2014</p>	



**U.S. ENVIRONMENTAL PROTECTION
AGENCY**

**Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460**

**EPA Registration
Number:**

82633-20

Date of Issuance:

FEB 11 2014

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Sharda Dicamba Technical

Name and Address of Registrant (include ZIP Code):

Sharda Worldwide Exports Pvt. Ltd
Mumbai, India
c/o Wagner Regulatory Associates
P. O. Box 640
Hockessin, DE 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

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1. Submit and/or cite all data required for the registration/ reregistration review of your product when the Agency requires all registrants of similar products to submit data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
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Enclosure

Signature of Approving Official:

Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

FEB 11 2014

